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(54) **FLEXIBLE TISSUE RASP**

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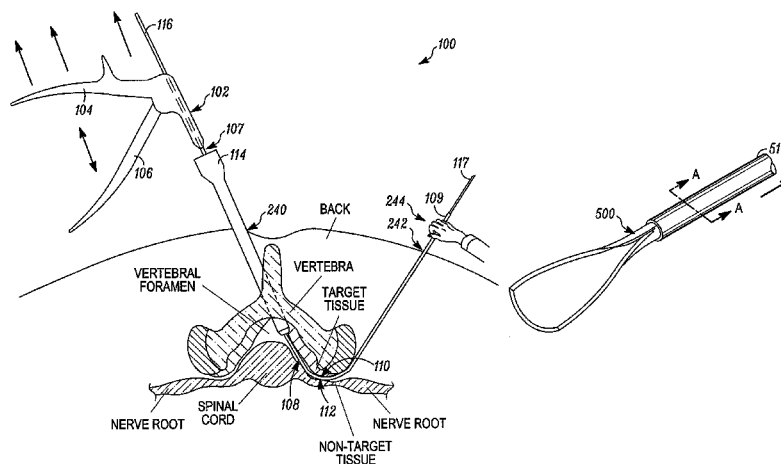
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(57)

ABSTRACT

Methods and devices are described for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis. In one embodiment, a method may include: advancing at least a distal portion of an elongate tissue modification device into an epidural space and between target tissue and non-target tissue in the spine; positioning the tissue modification device so that at least one abrasive surface of the device faces target tissue and at least one non-abrasive surface faces non-target tissue; applying tensioning force at or near separate distal and proximal portions of the tissue modification device; and translating the tissue modification device back and forth while maintaining at least some tensioning force to abrade at least a portion of the target tissue with the at least one abrasive surface. Unwanted damage to the non-target tissue may be prevented via the at least one non-abrasive surface.

19 Claims, 43 Drawing Sheets



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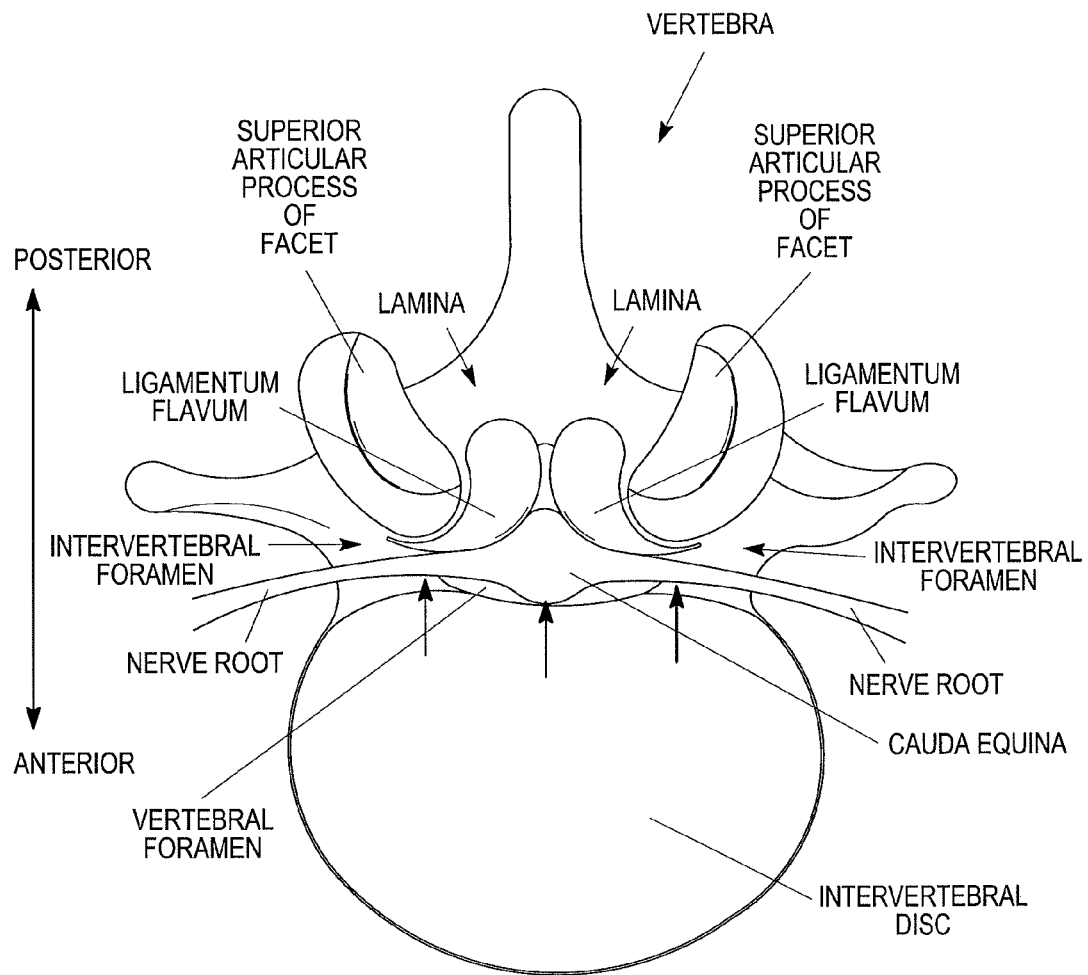
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*FIG. 1*

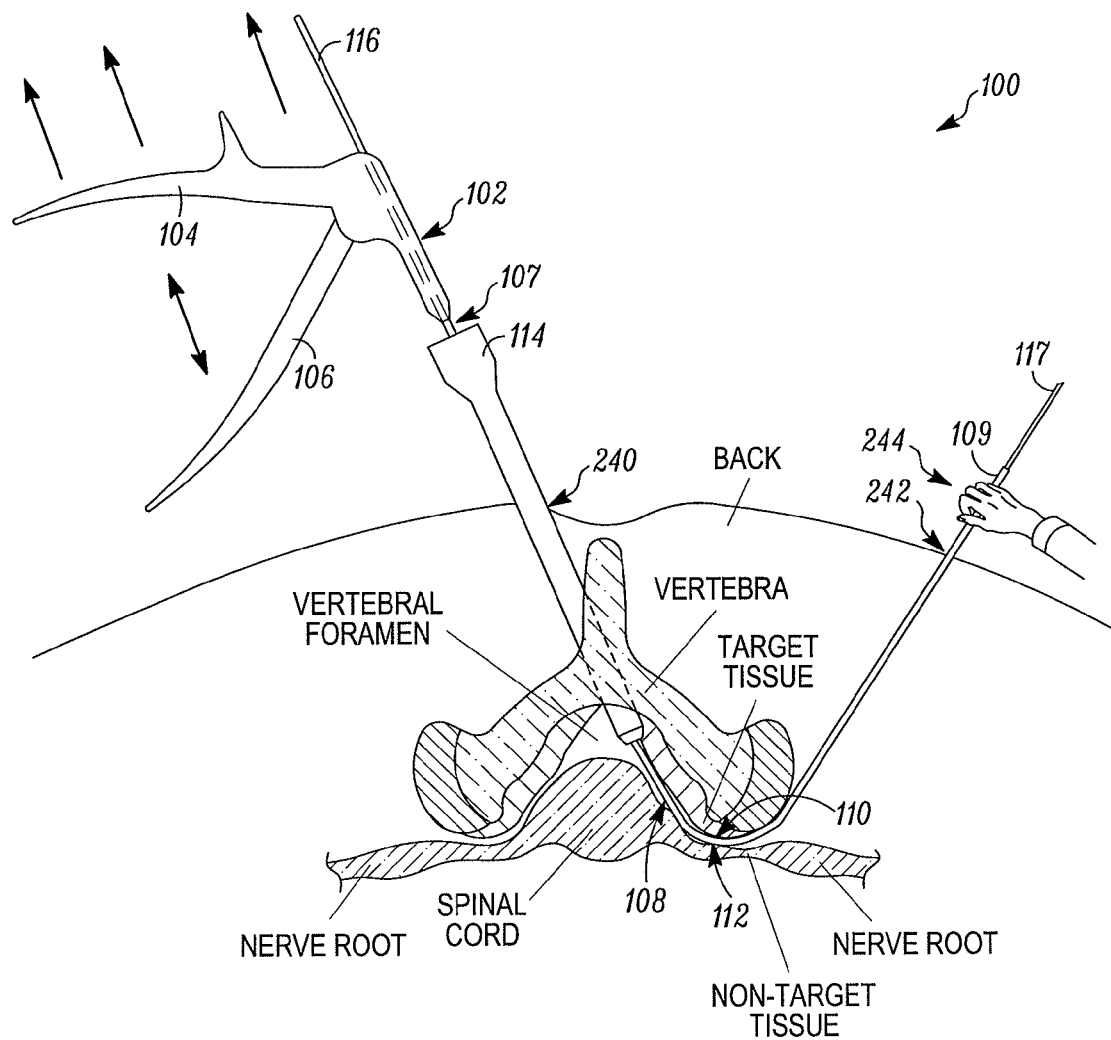


FIG. 2

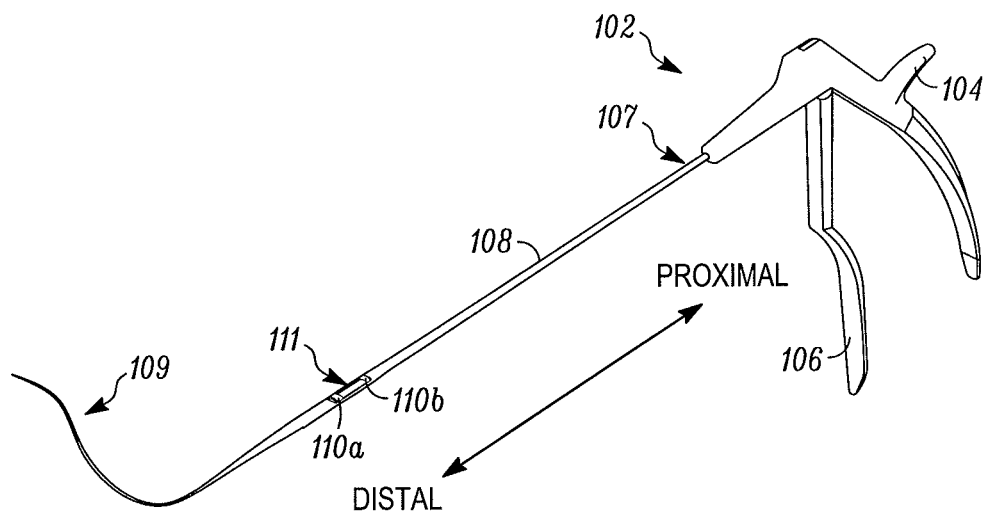


FIG. 3A

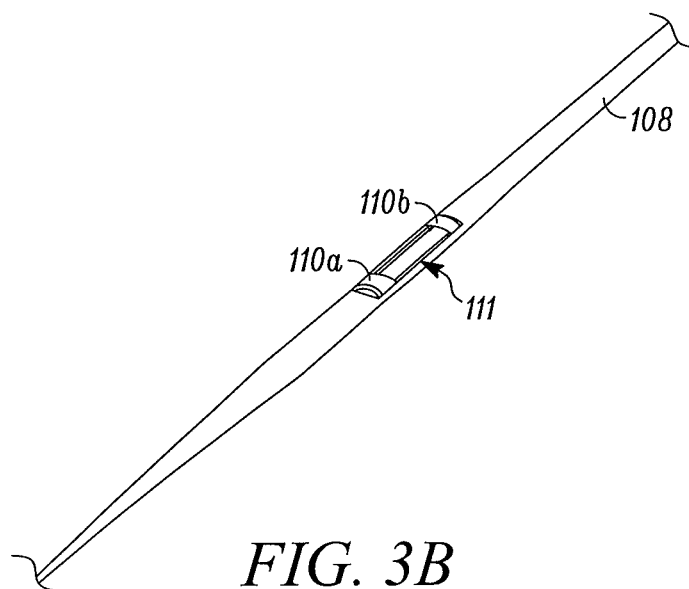


FIG. 3B

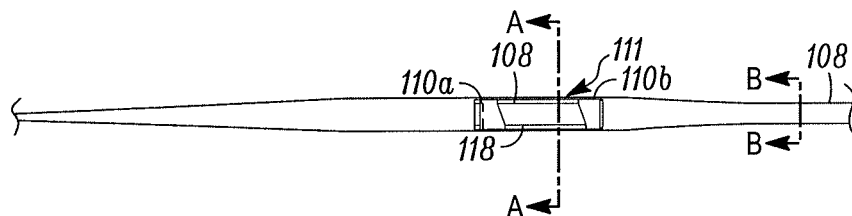


FIG. 3C

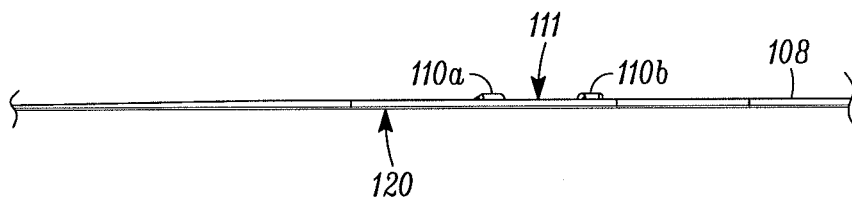
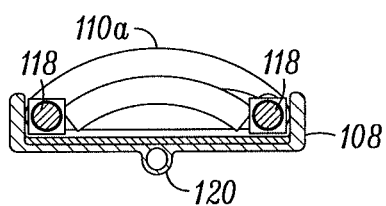
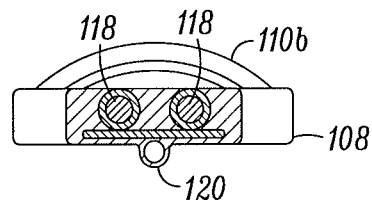


FIG. 3D



SECTION A-A

FIG. 3E



SECTION B-B

FIG. 3F

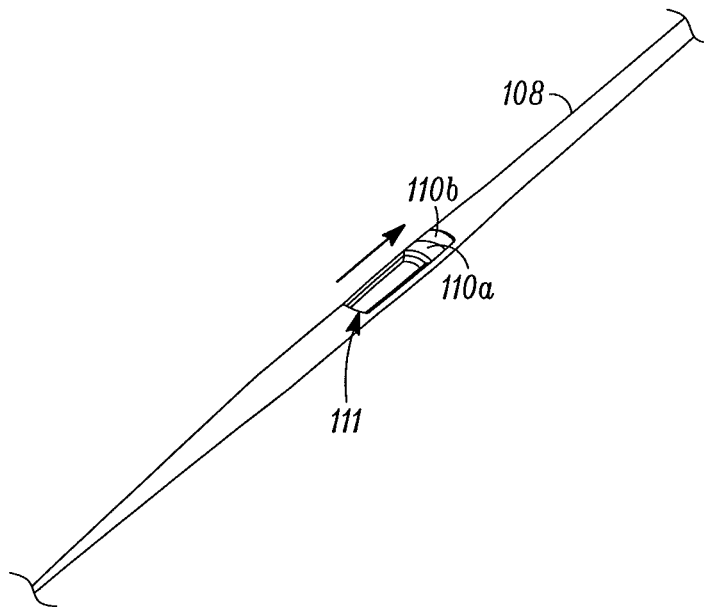


FIG. 3G

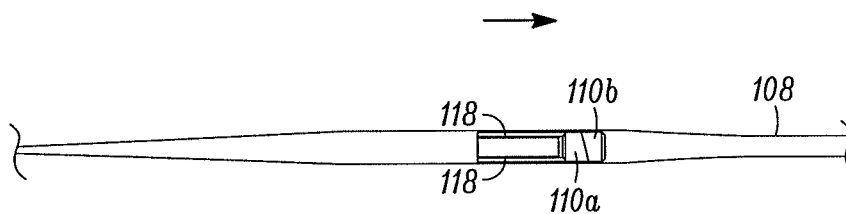


FIG. 3H

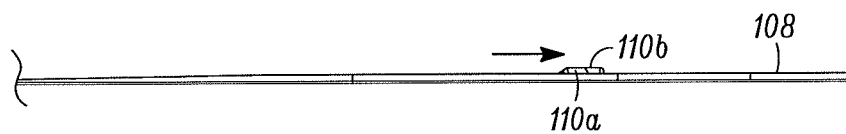


FIG. 3I

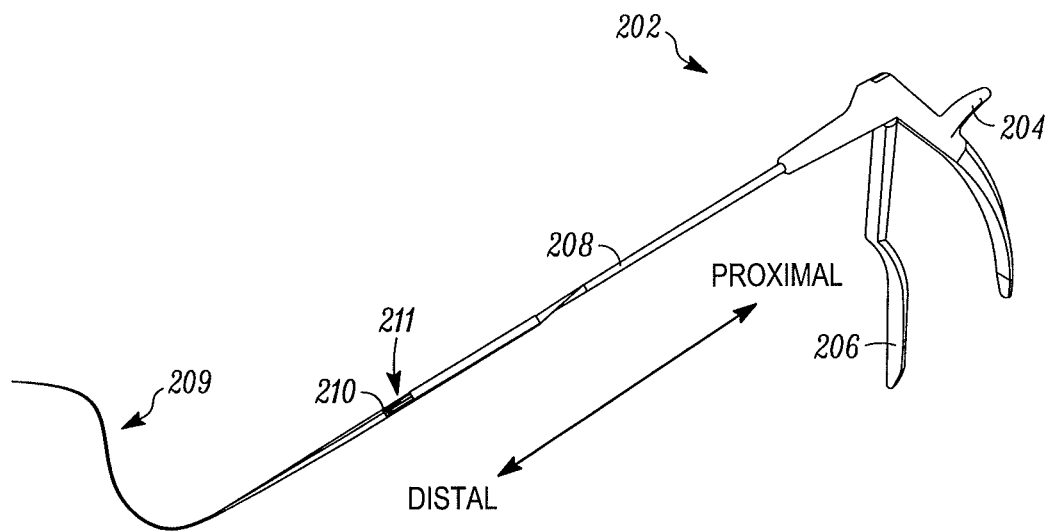


FIG. 4A

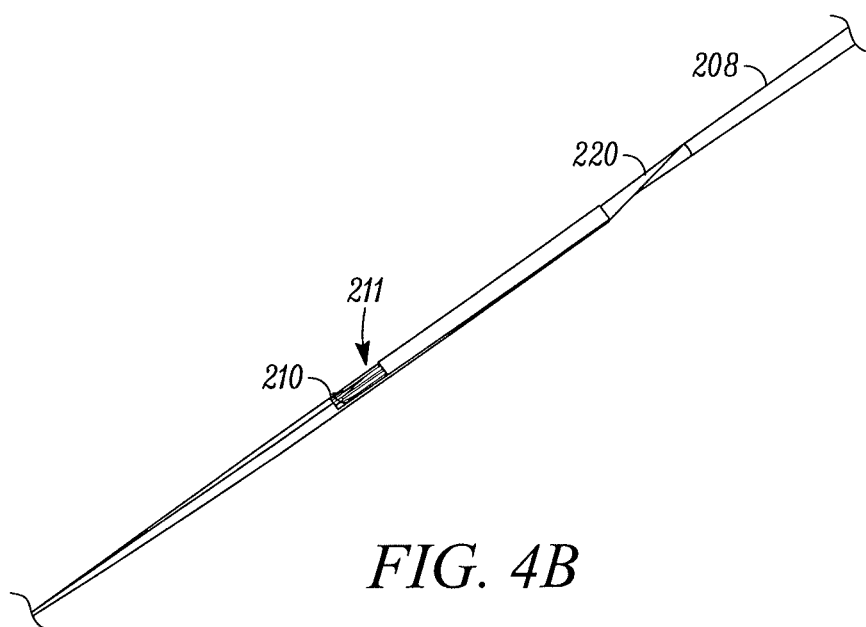


FIG. 4B

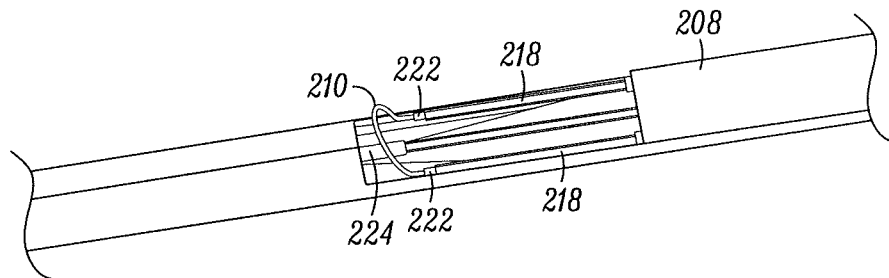


FIG. 4C

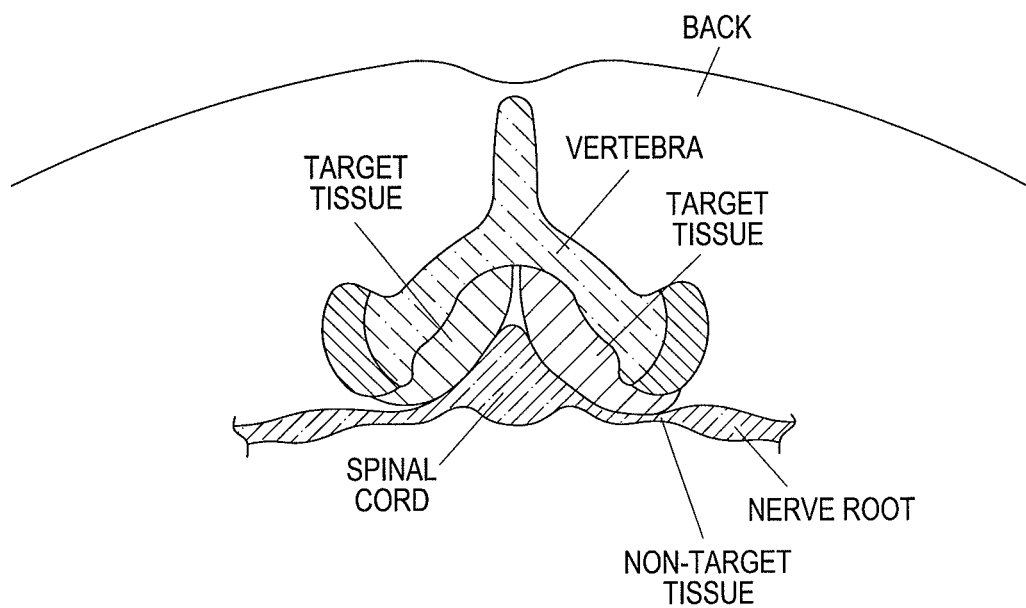


FIG. 5A

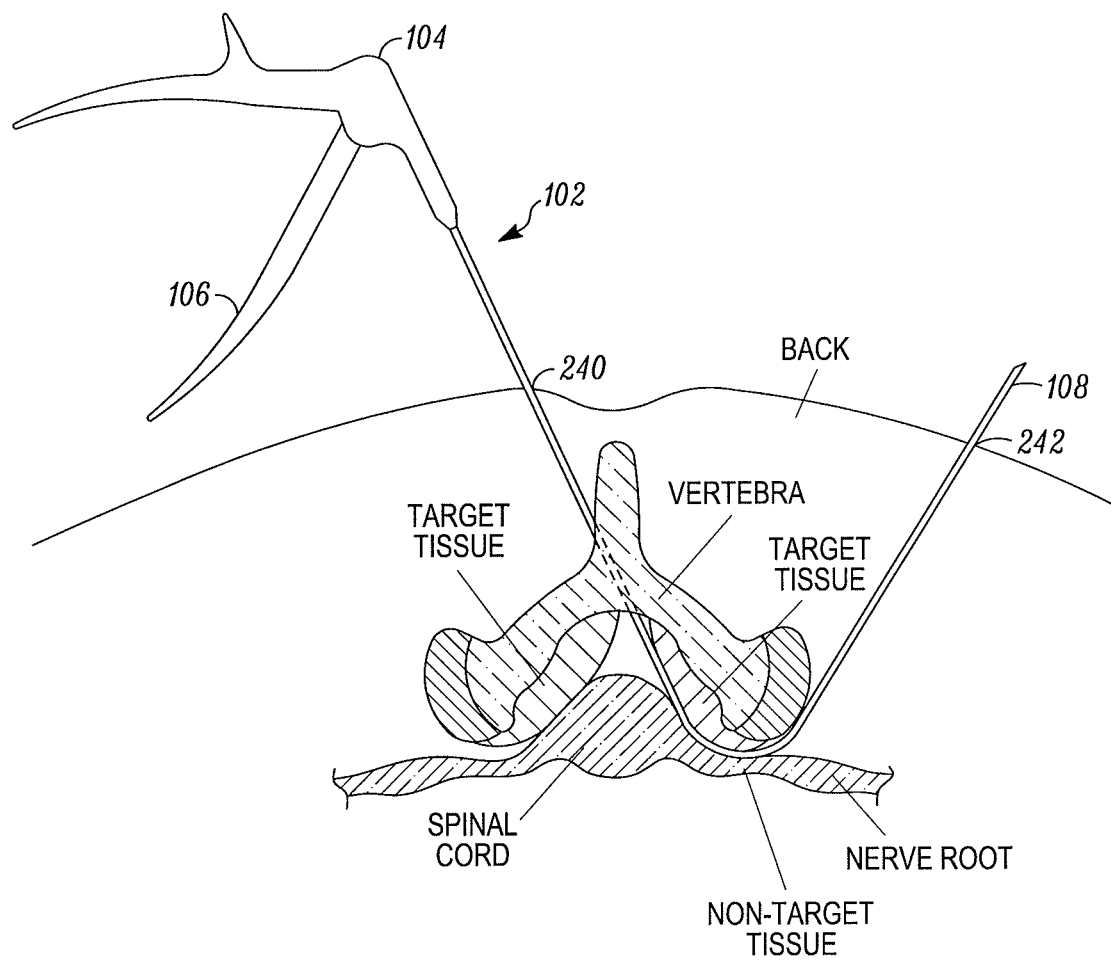


FIG. 5B

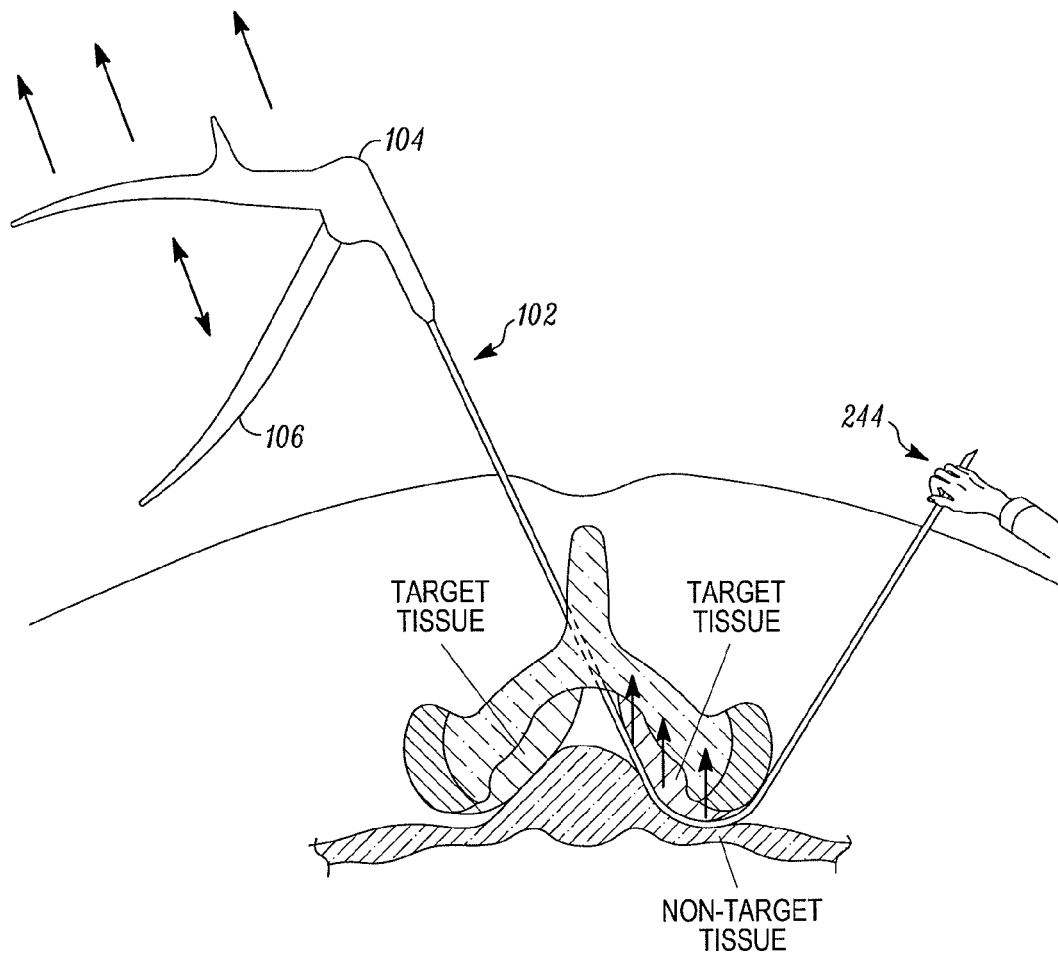


FIG. 5C

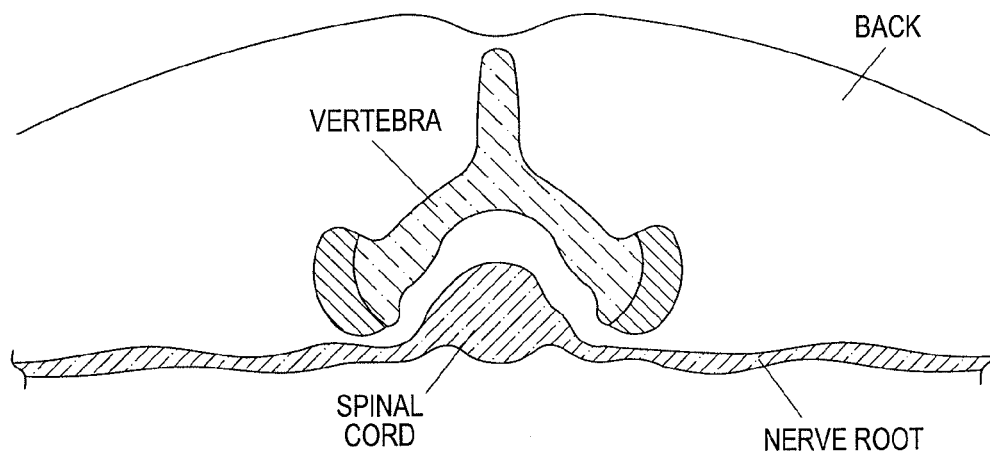


FIG. 5D

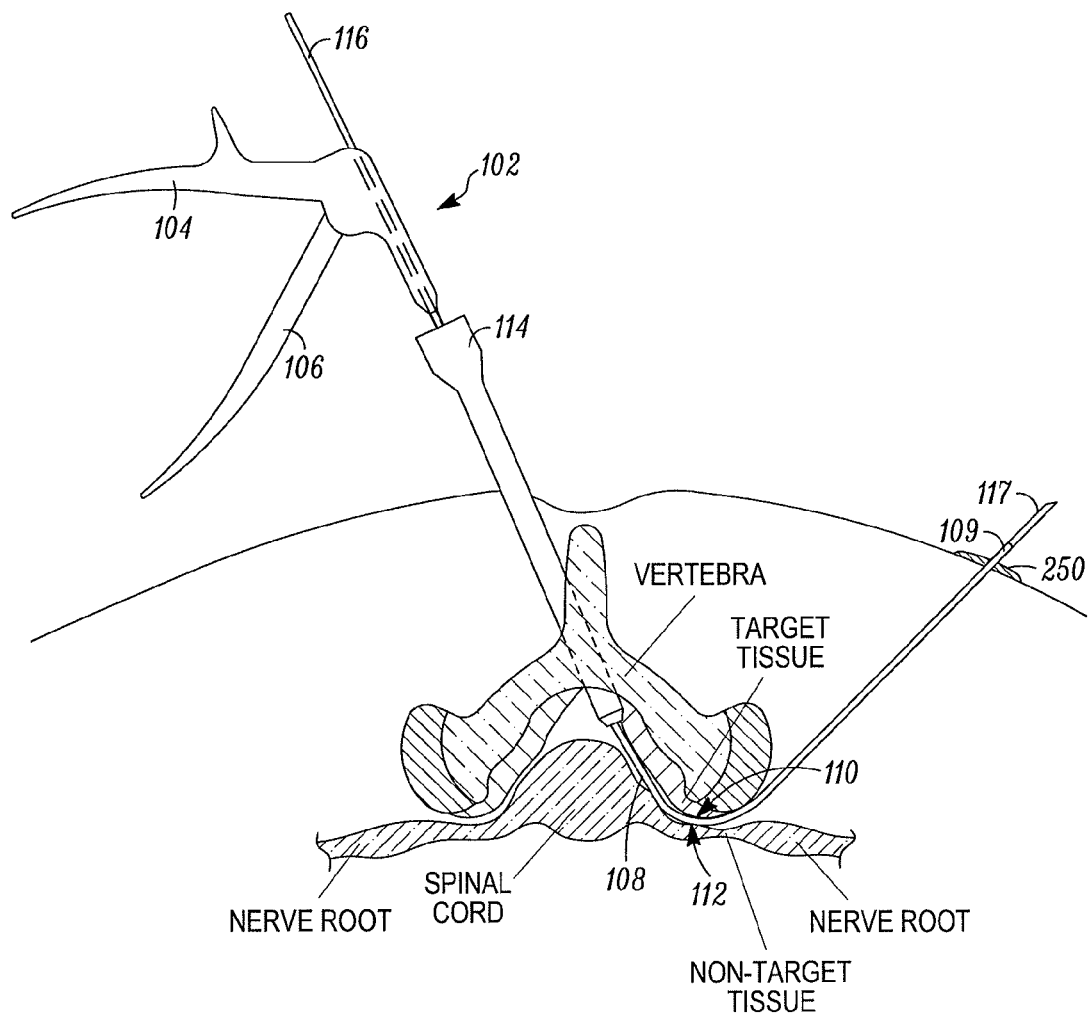


FIG. 6A

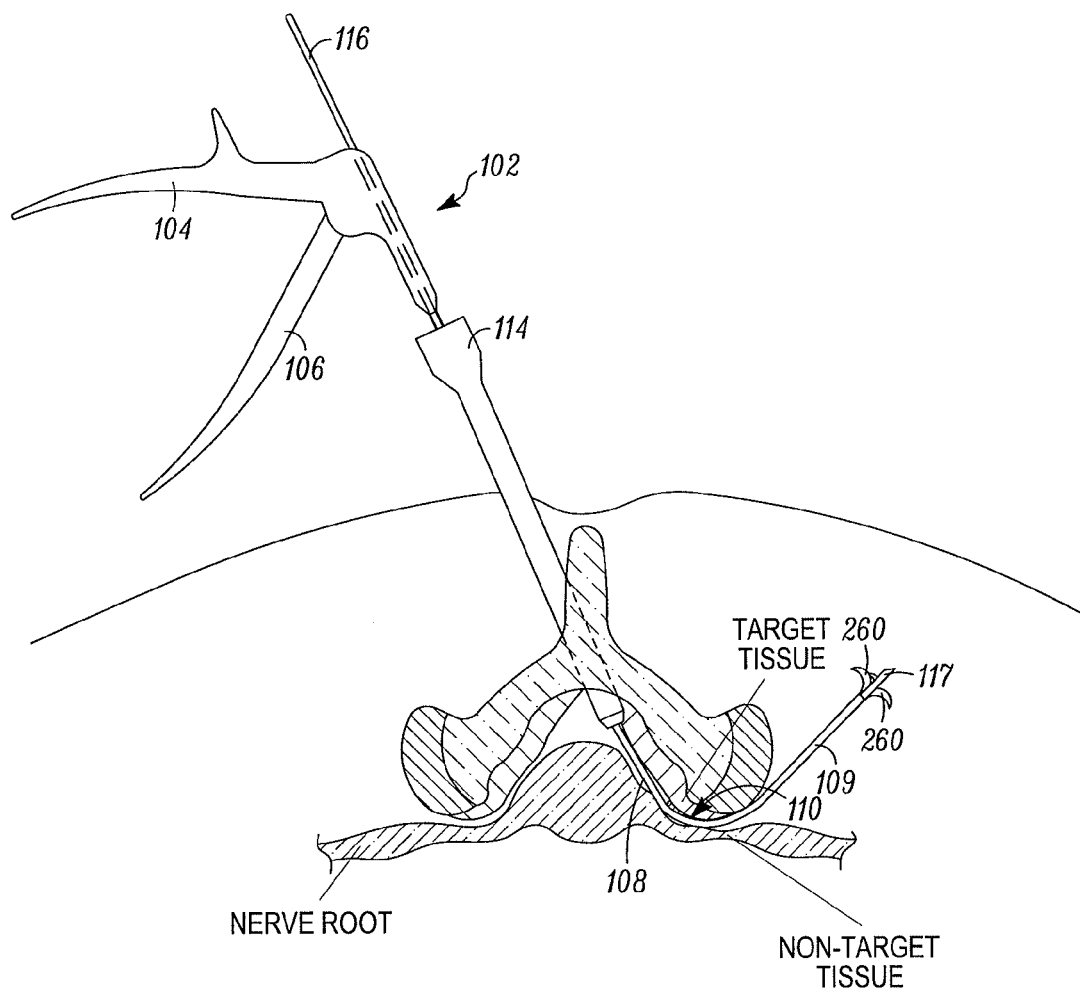
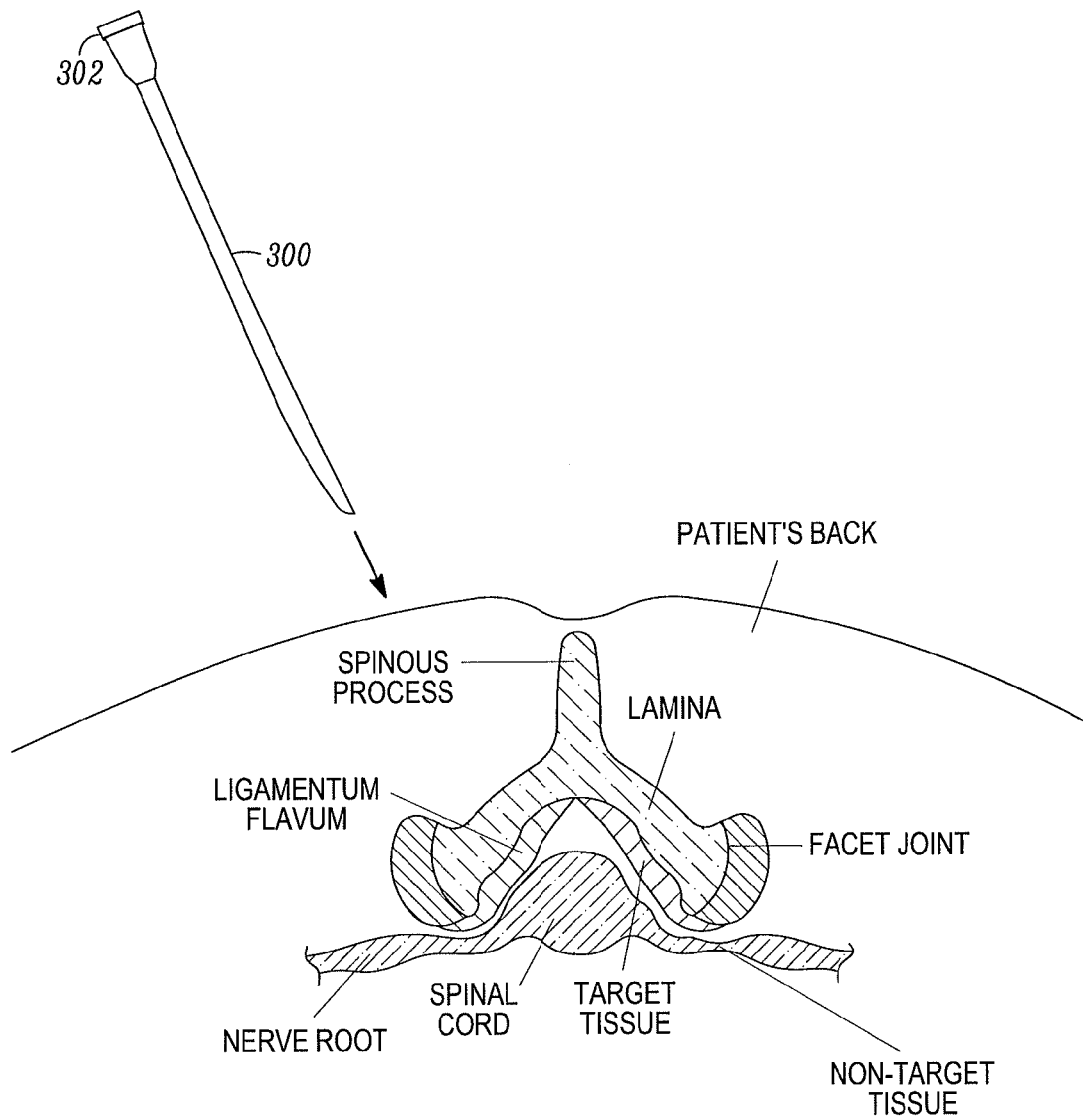
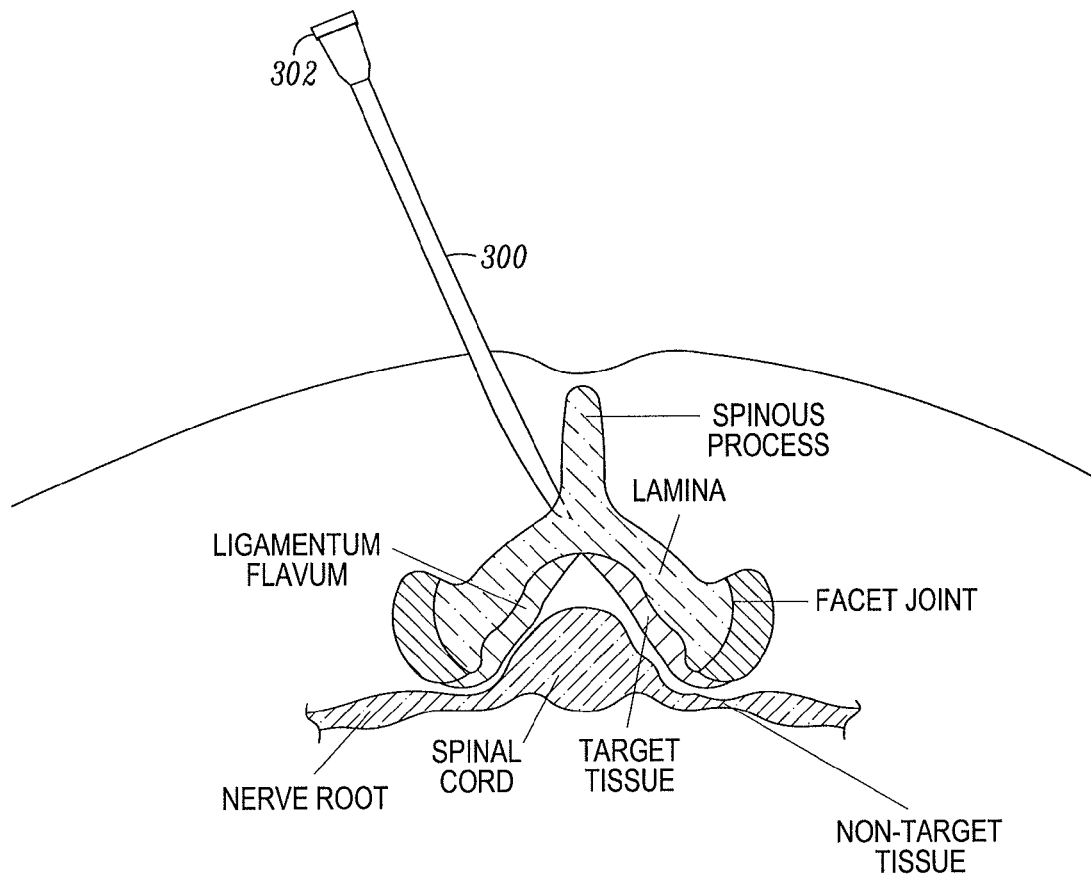
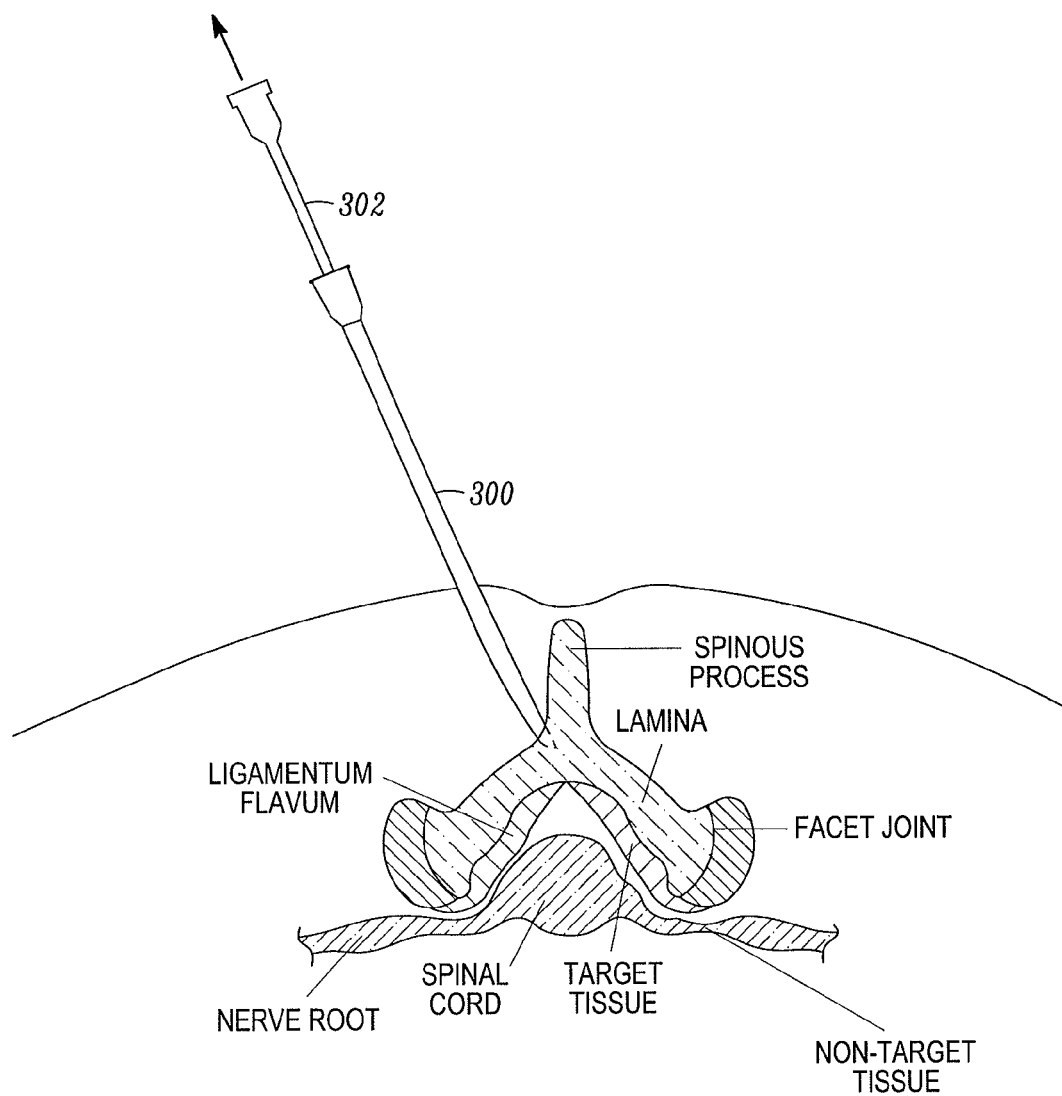
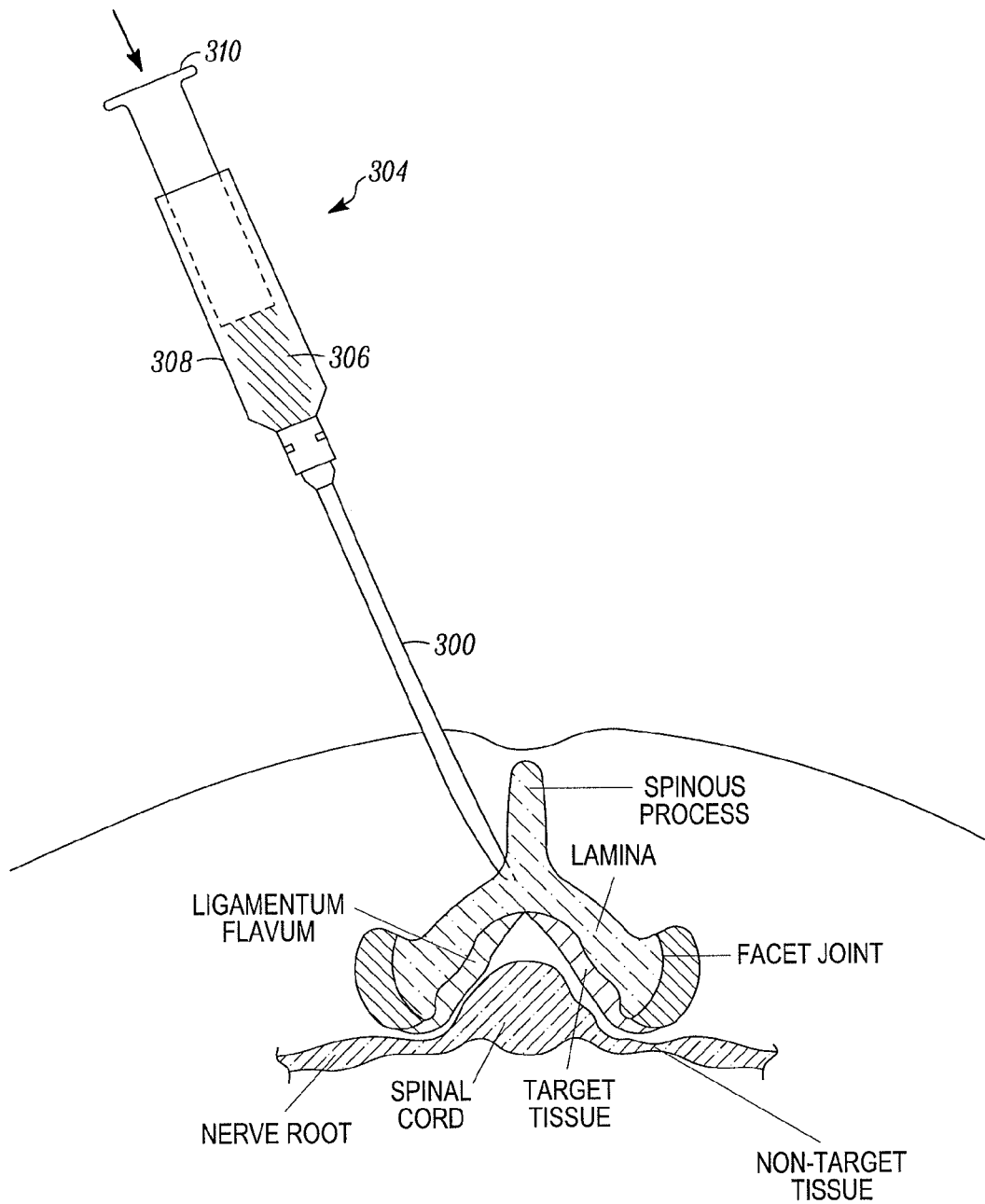


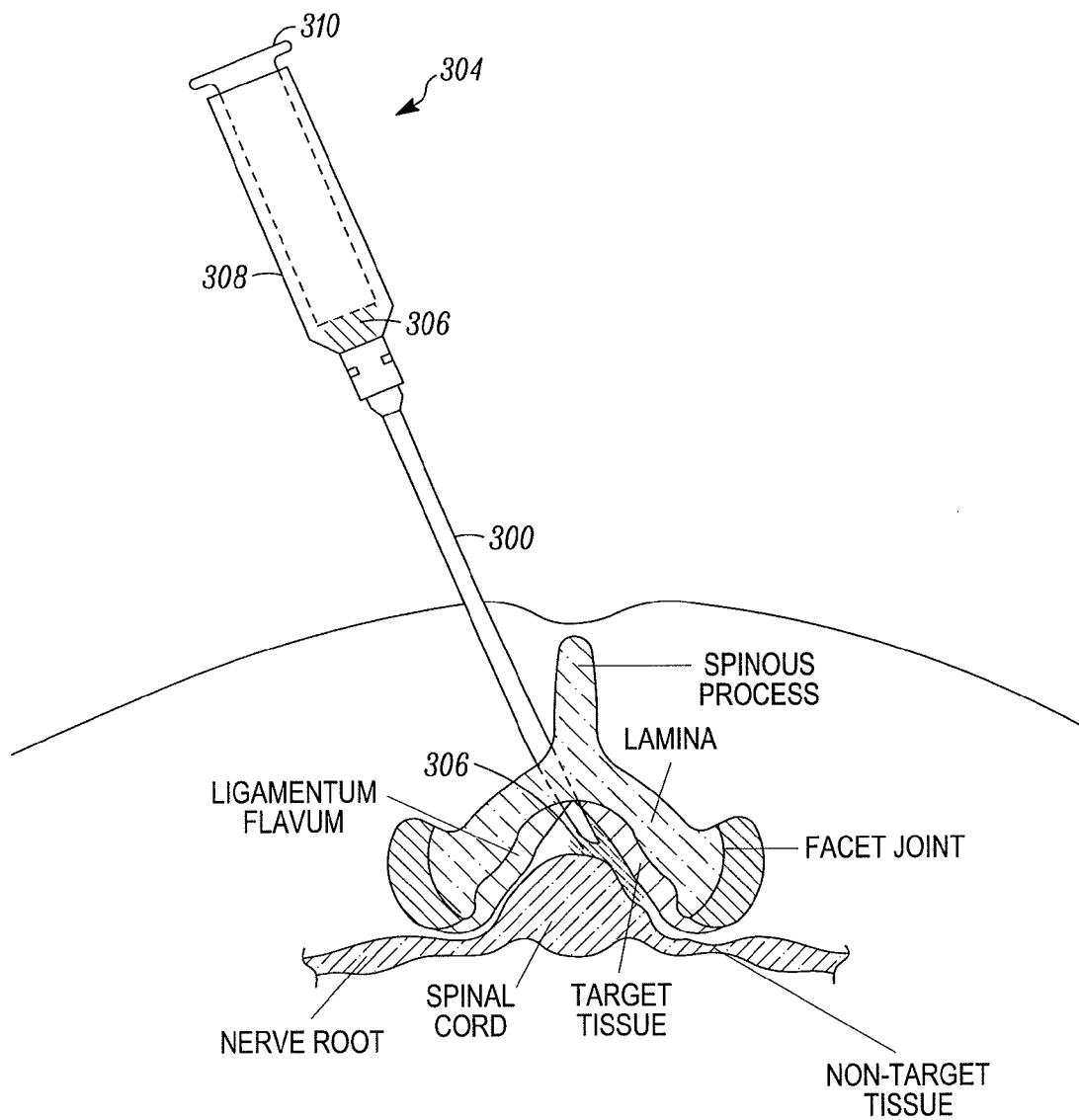
FIG. 6B

*FIG. 7A*

*FIG. 7B*

*FIG. 7C*

*FIG. 7D*

*FIG. 7E*

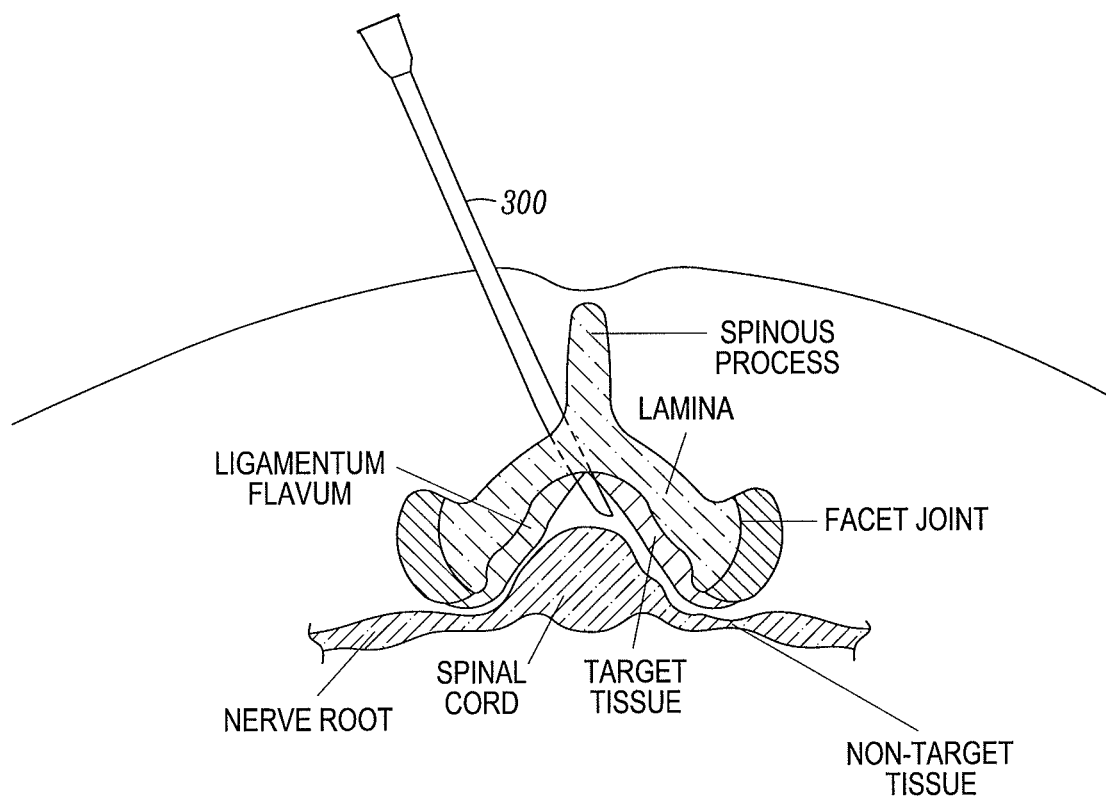


FIG. 7F

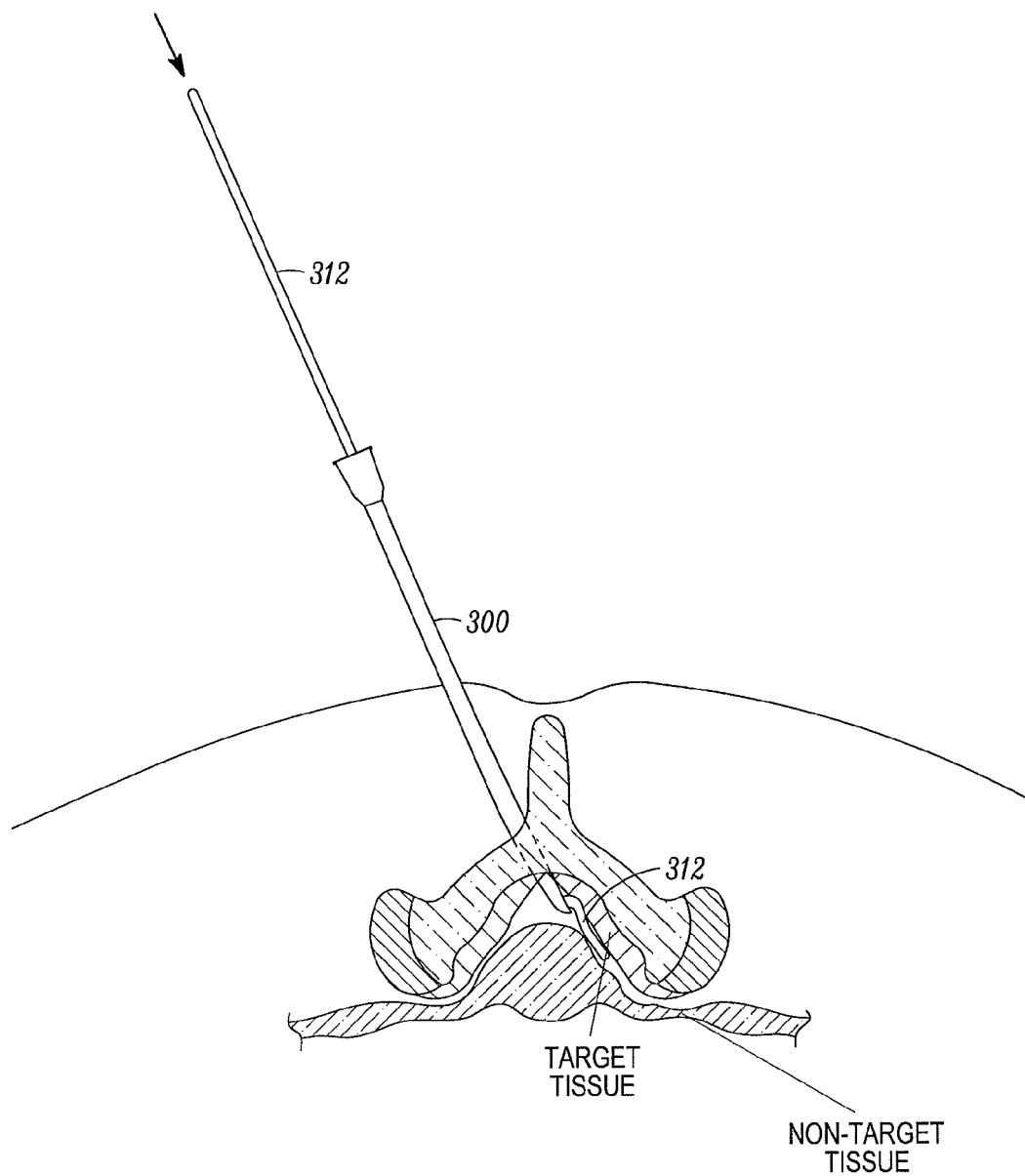


FIG. 7G

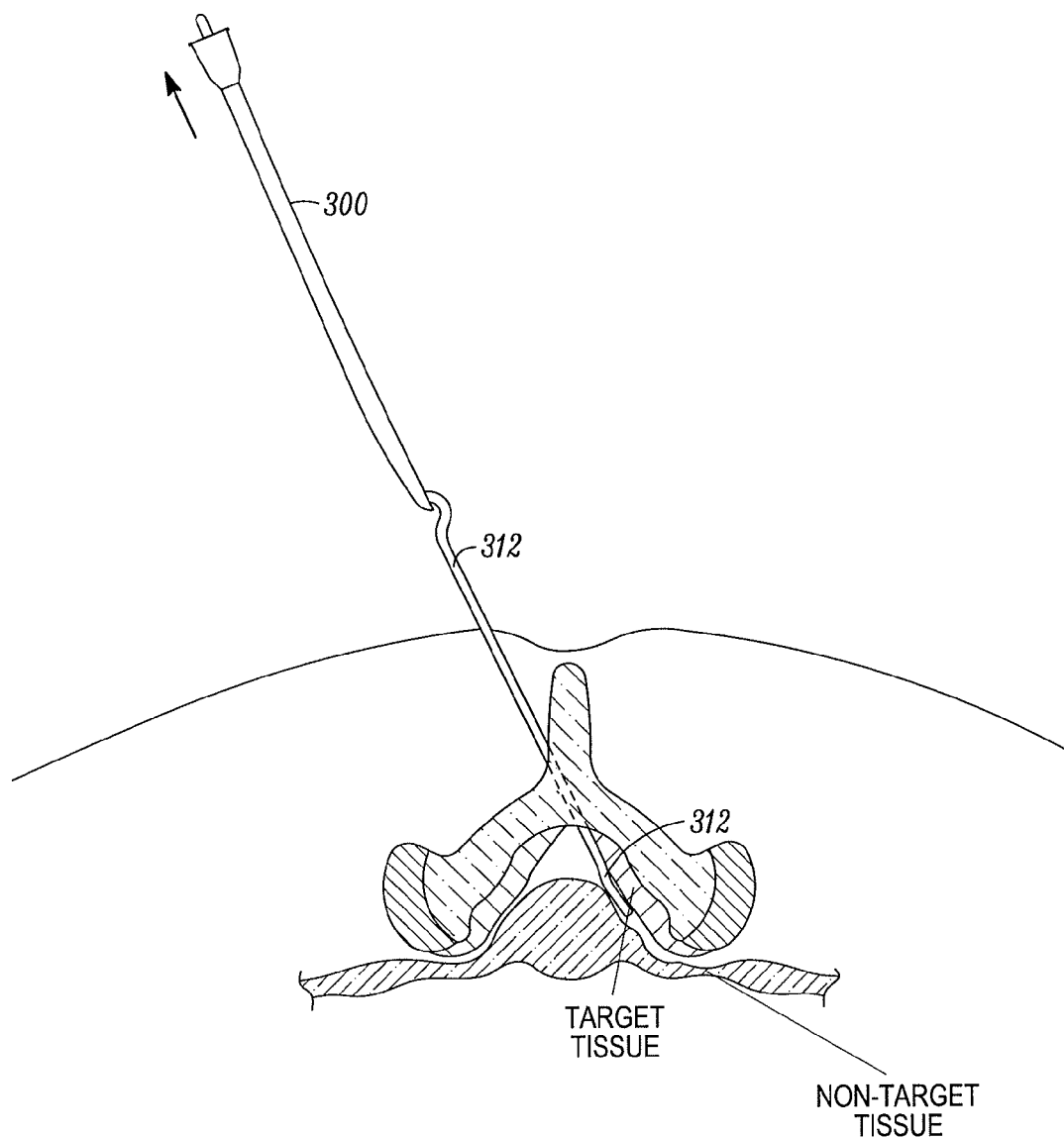


FIG. 7H

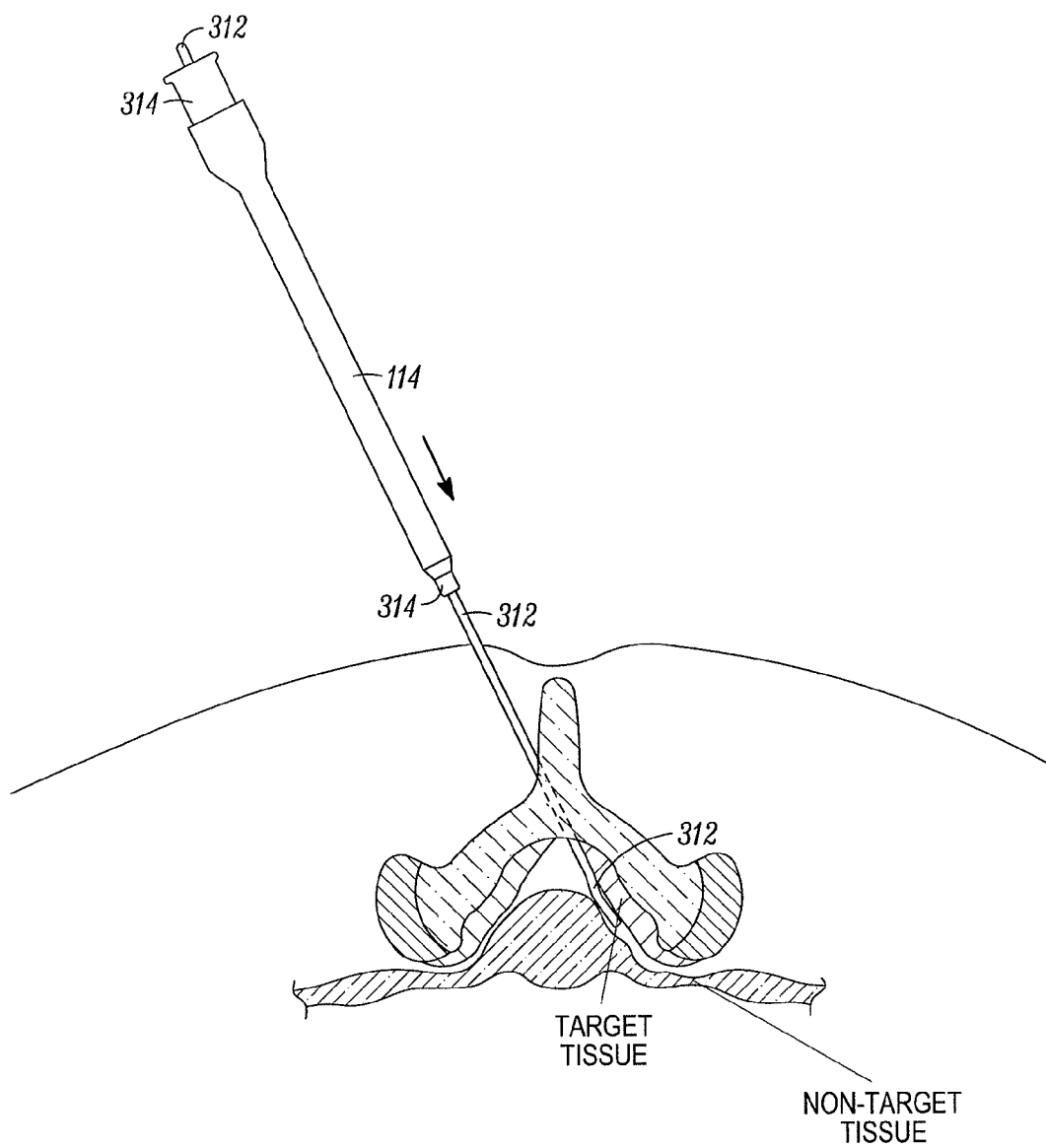


FIG. 7I

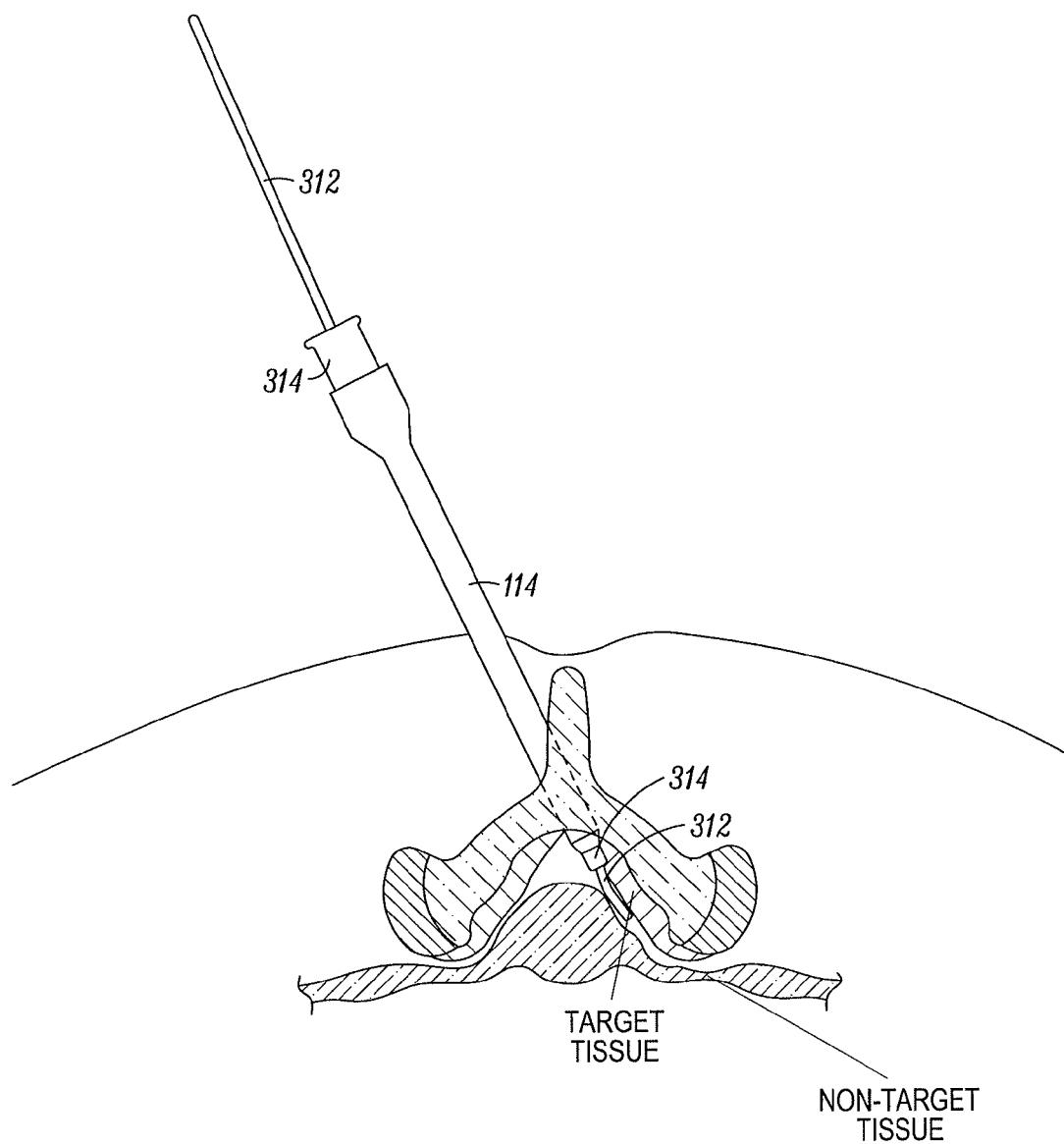


FIG. 7J

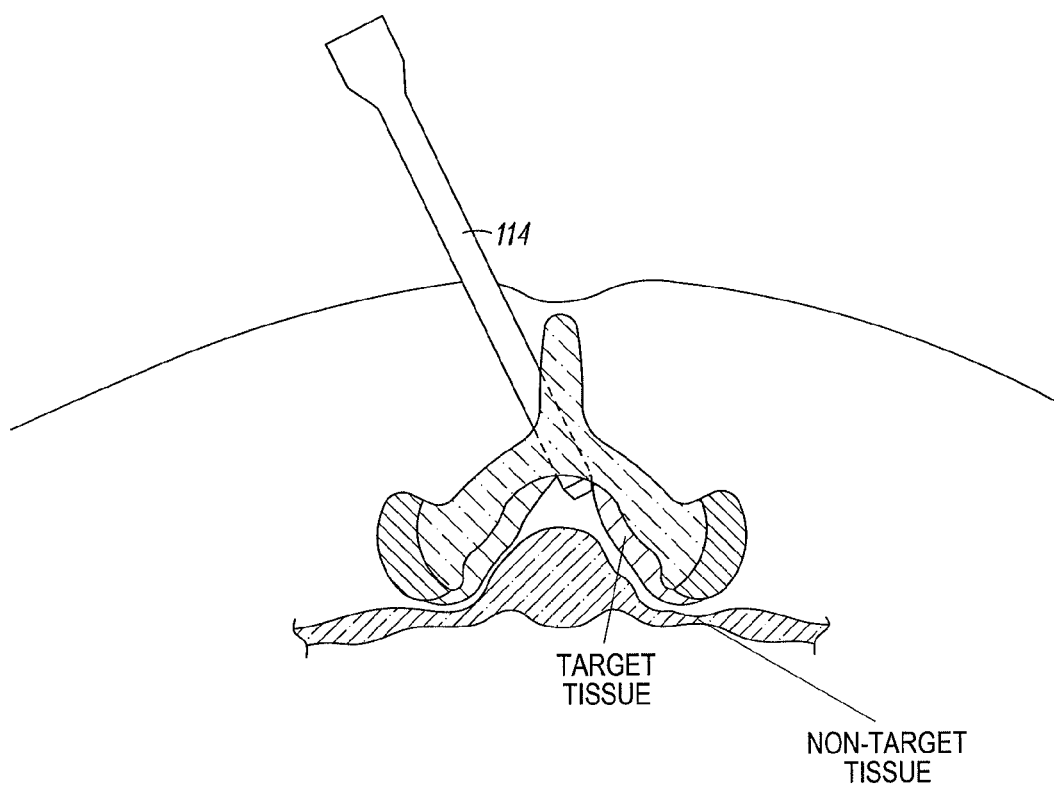


FIG. 7K

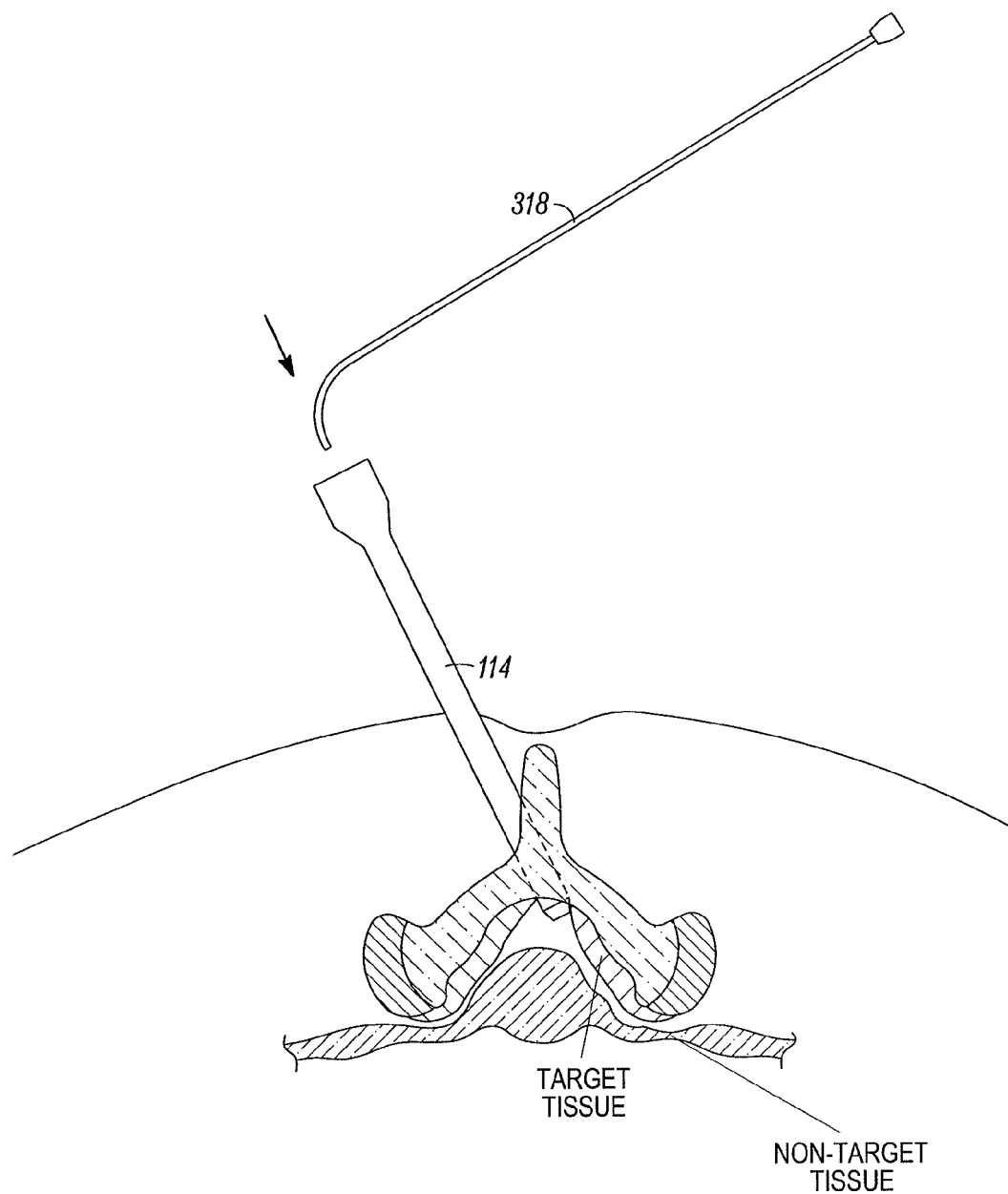


FIG. 7L

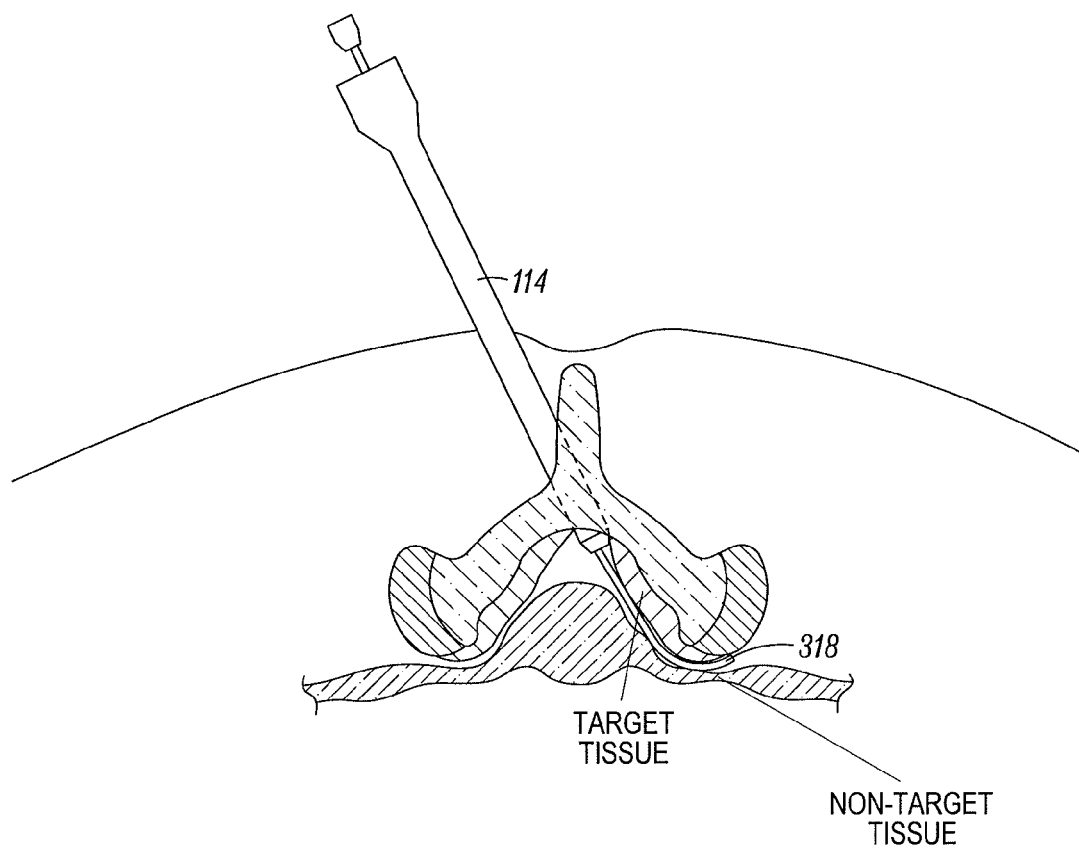


FIG. 7M

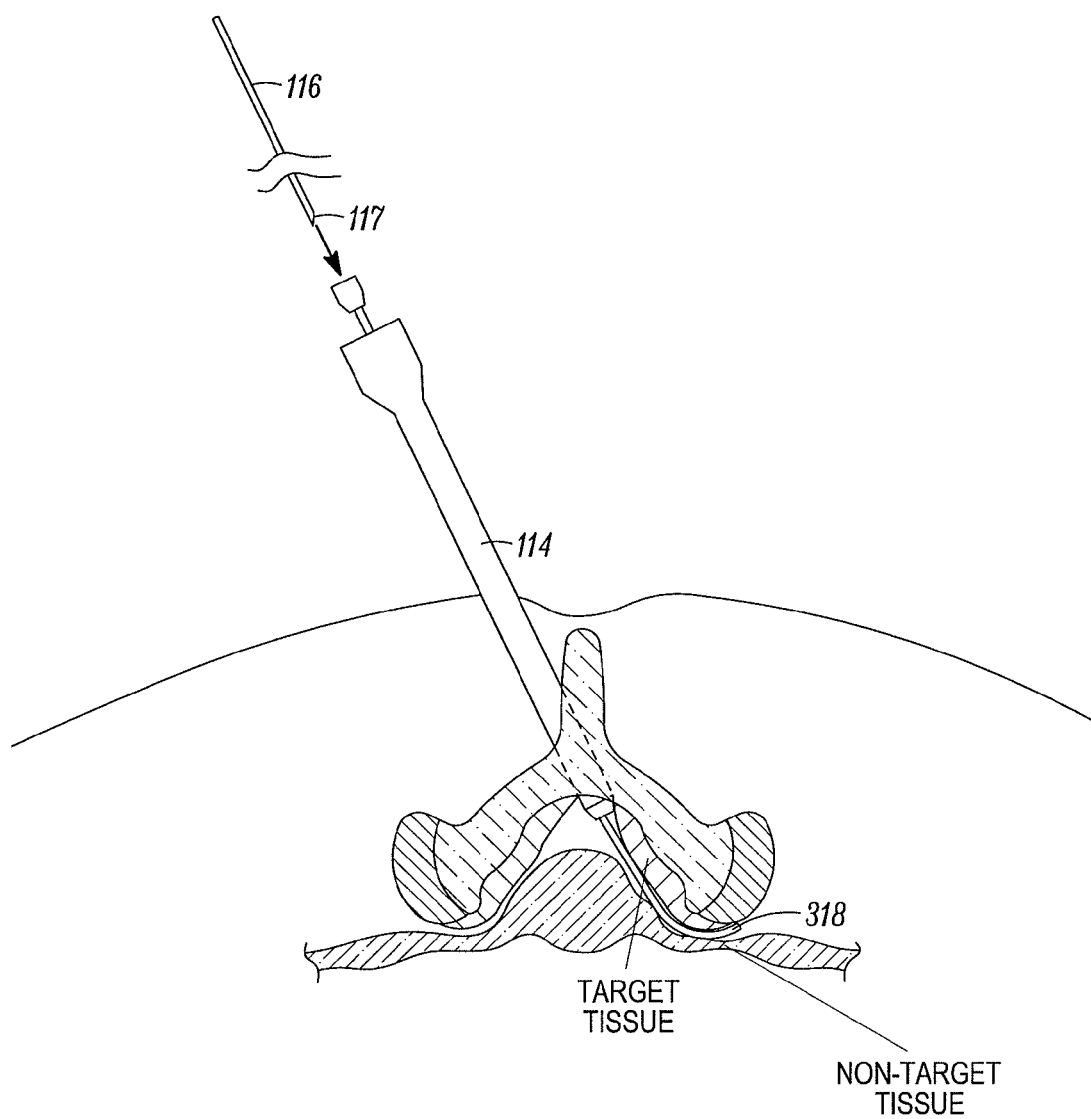


FIG. 7N

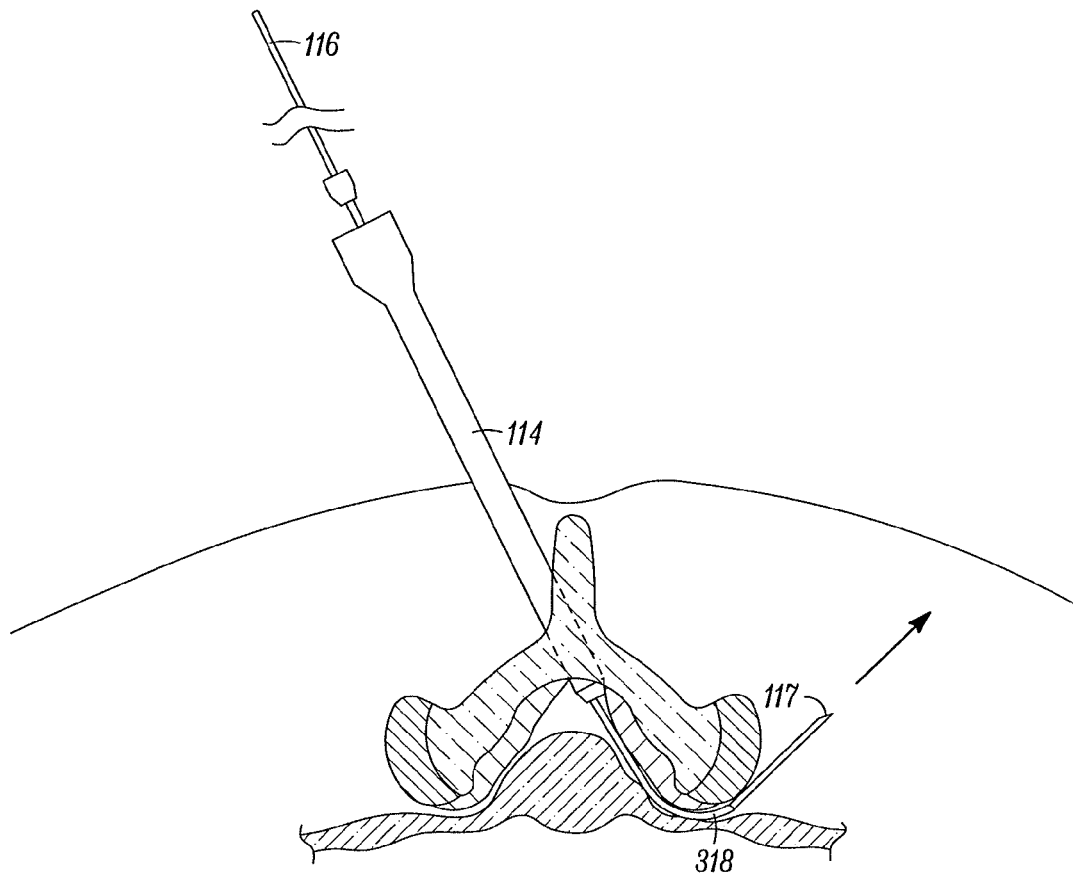


FIG. 70

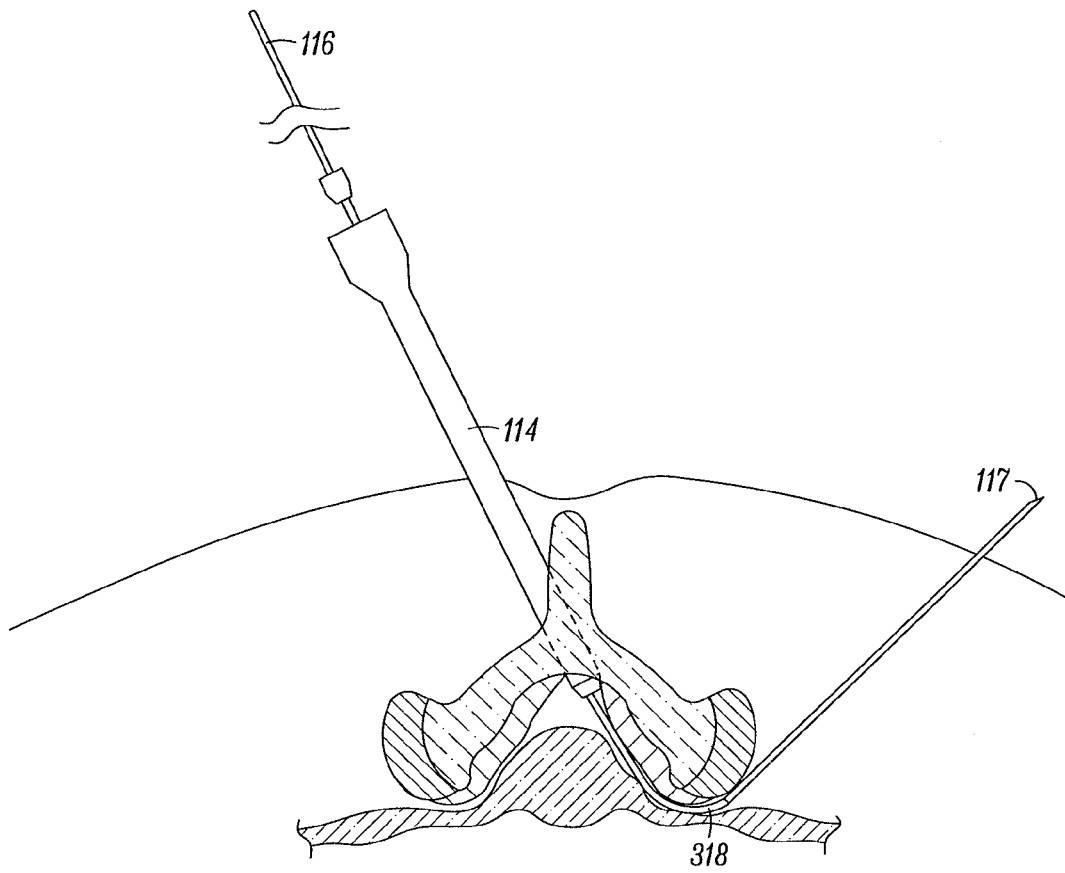


FIG. 7P

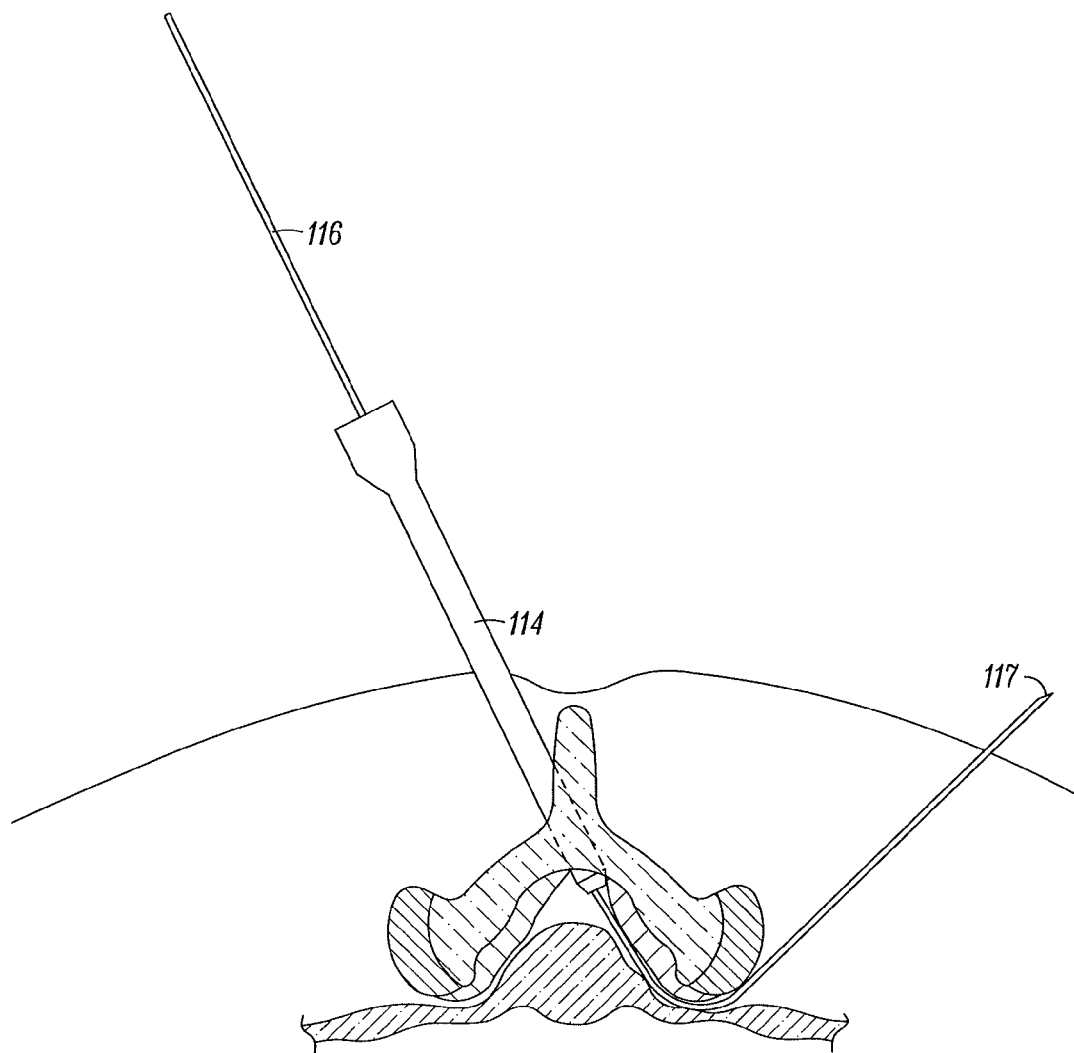


FIG. 7Q

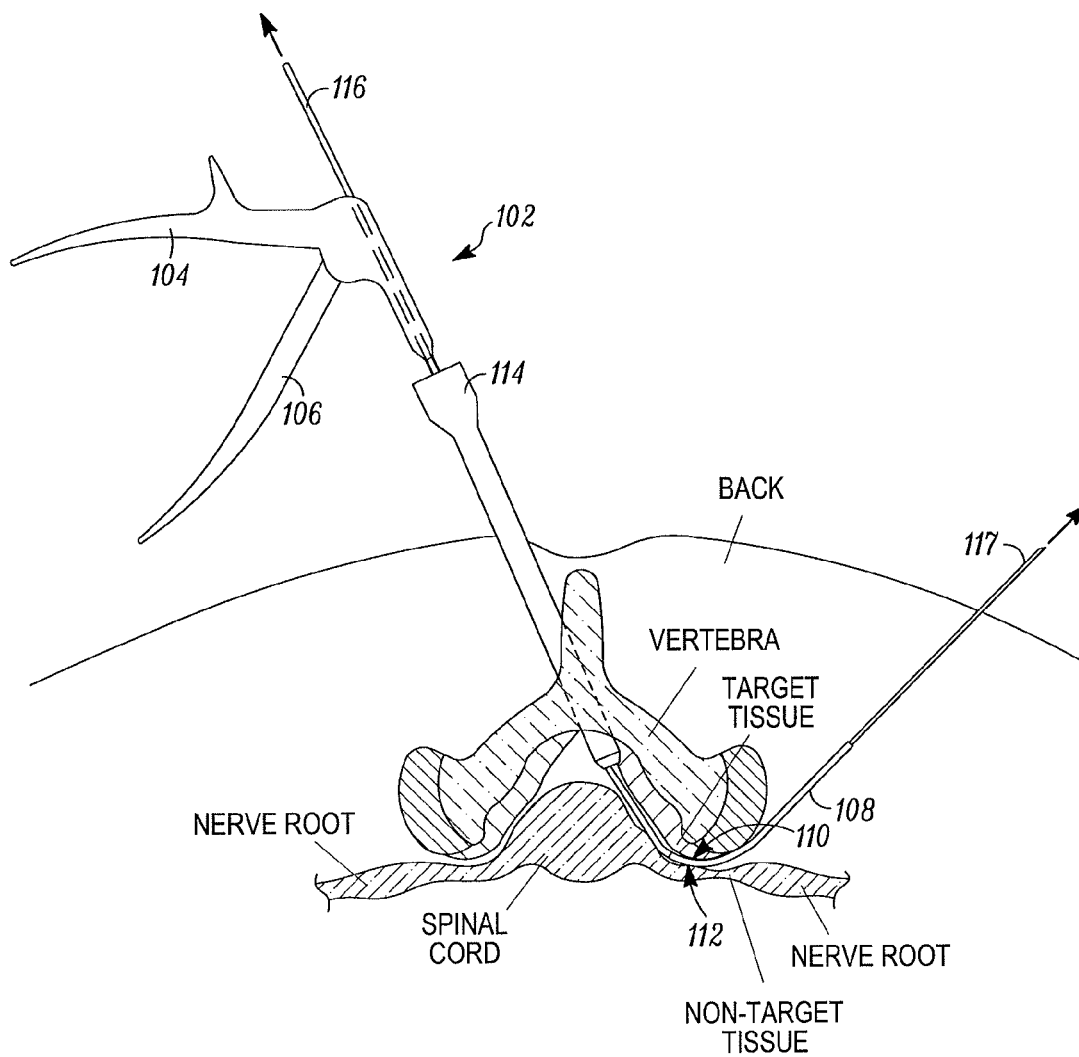


FIG. 7R

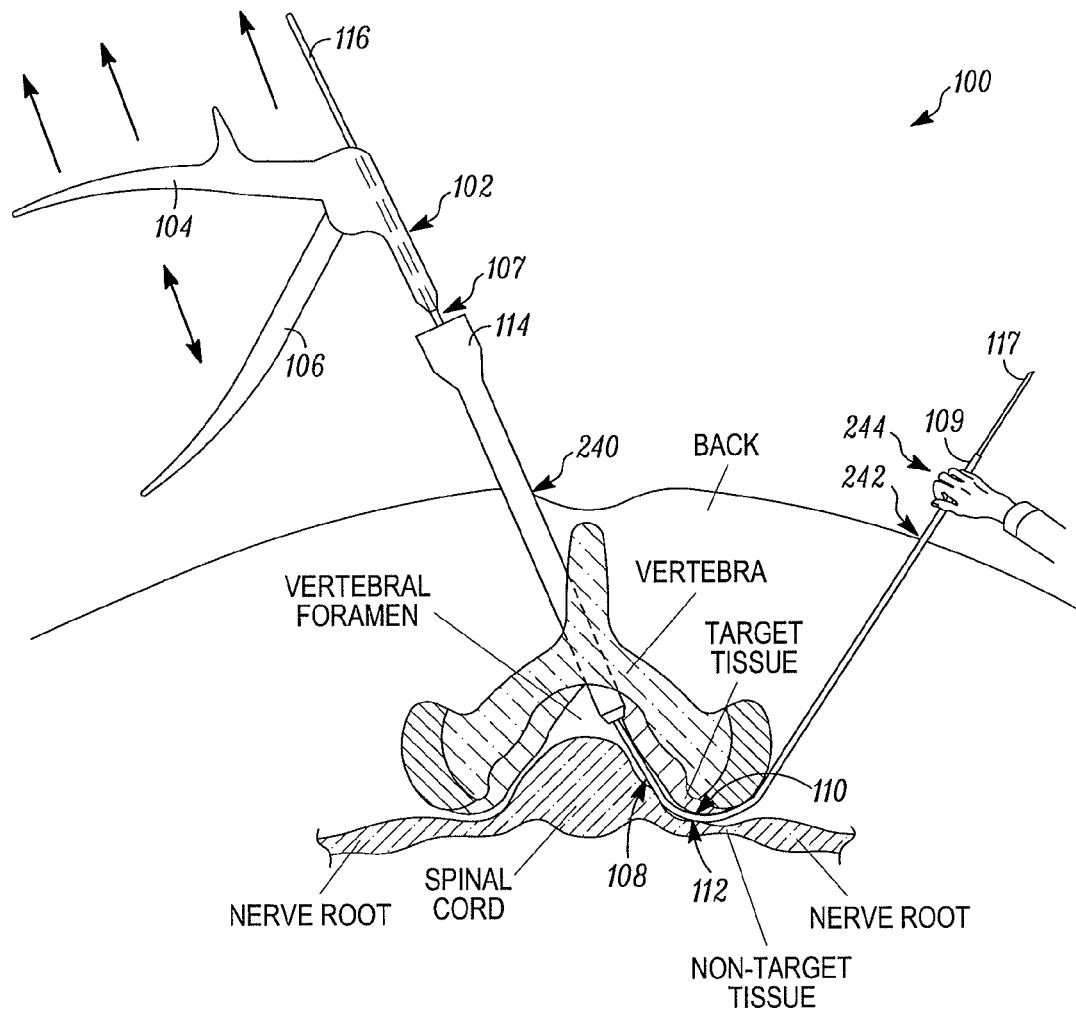


FIG. 7S

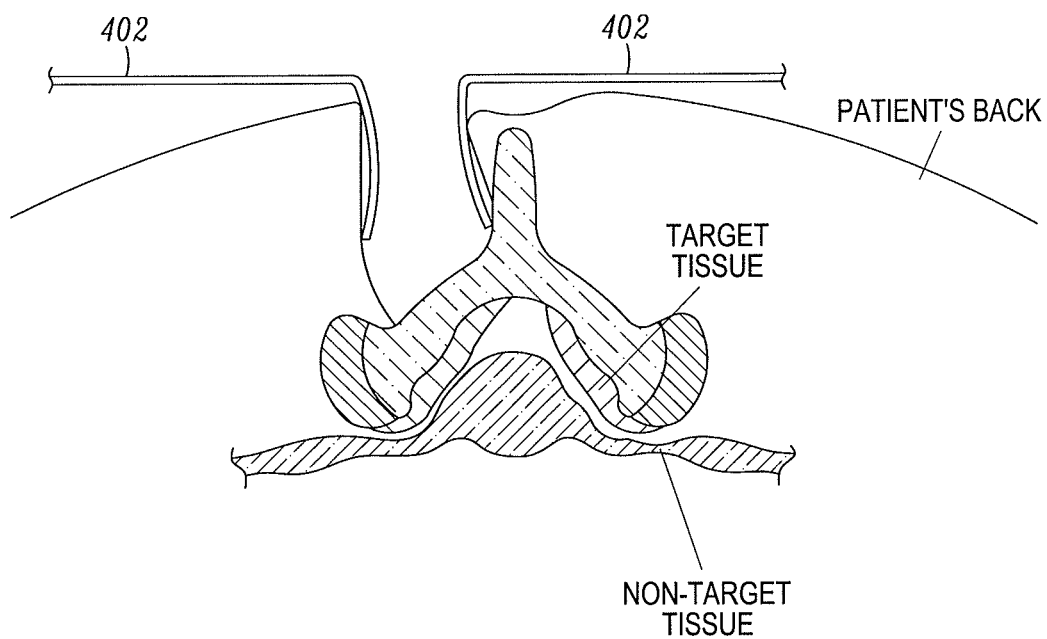


FIG. 8A

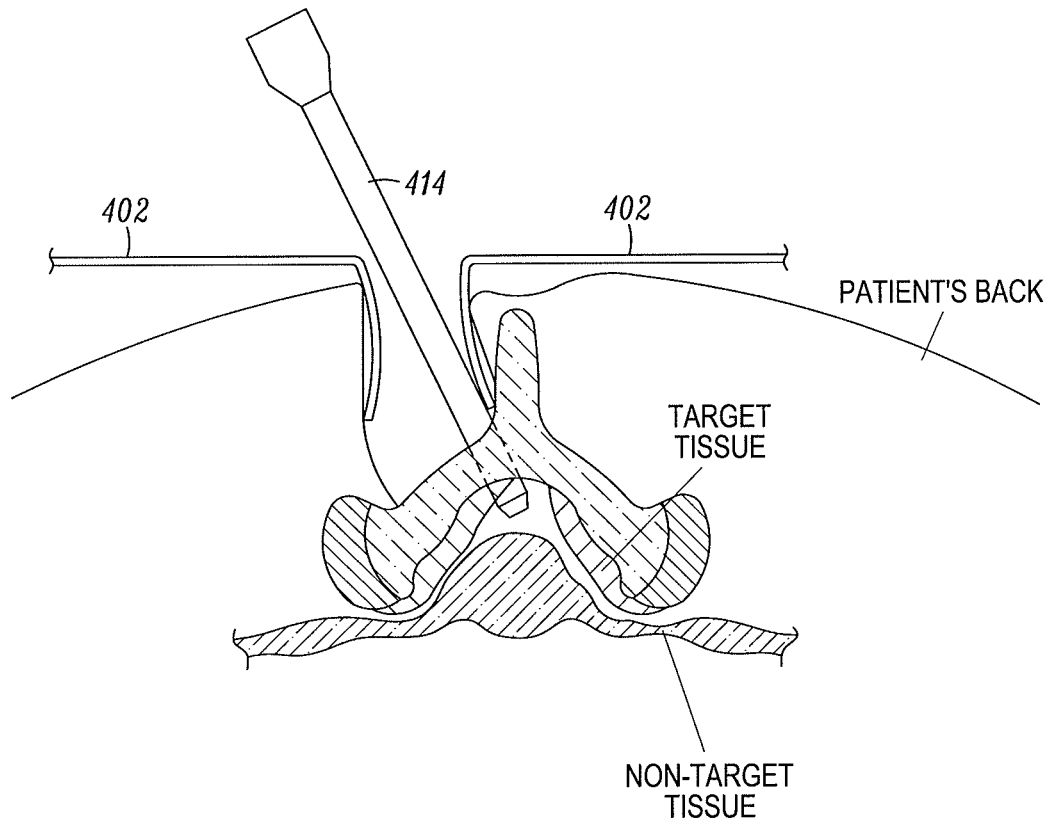


FIG. 8B

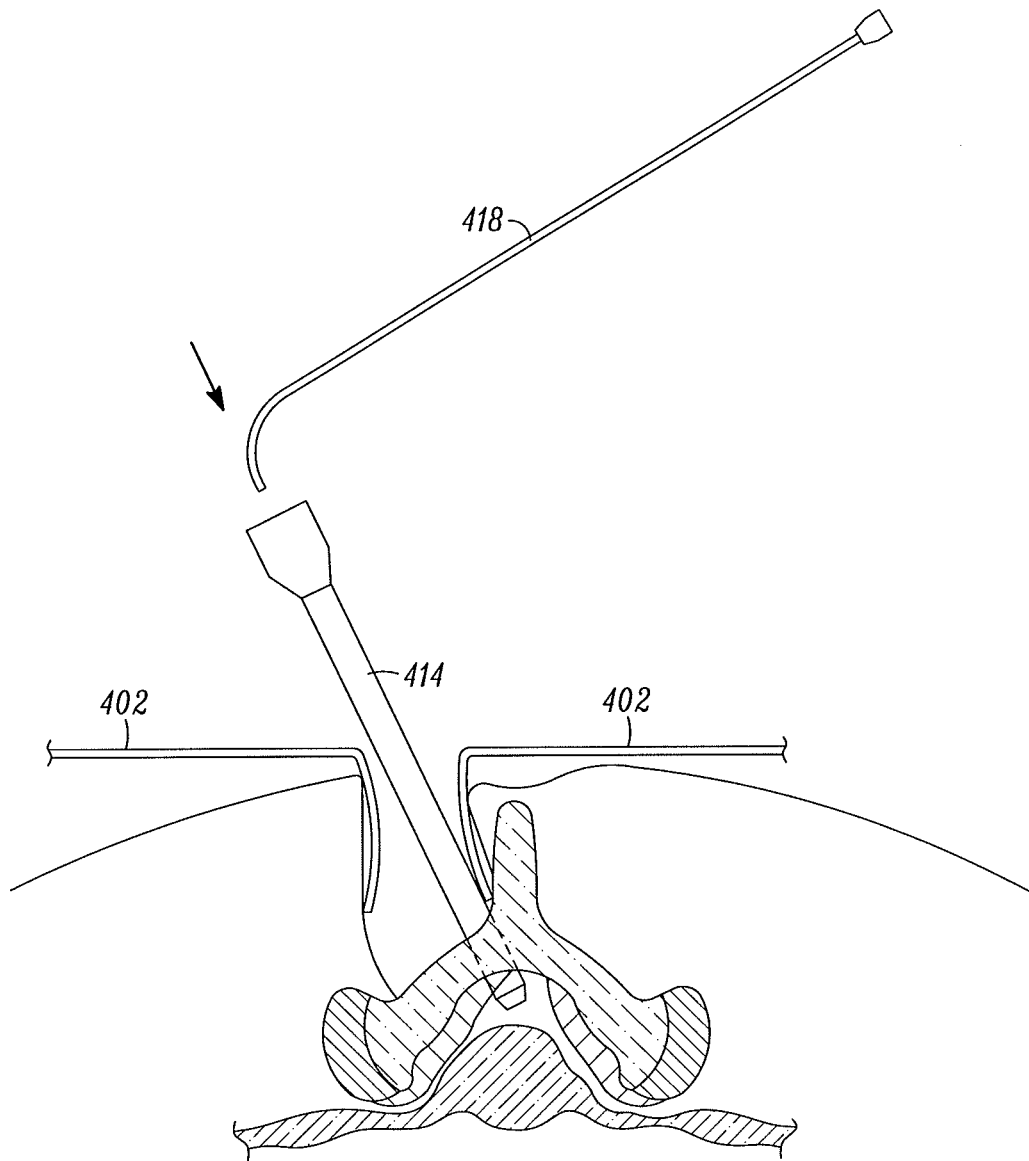


FIG. 8C

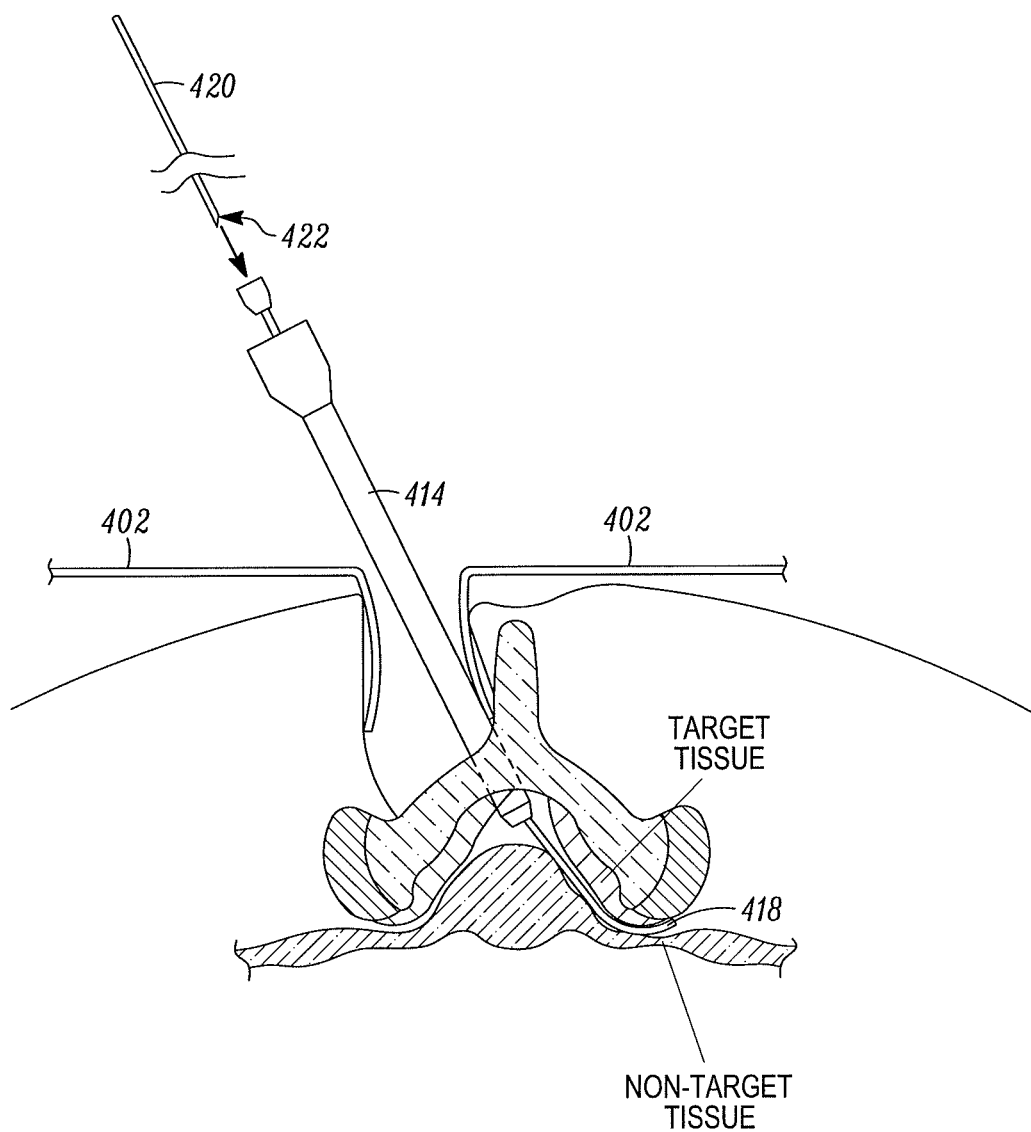


FIG. 8D

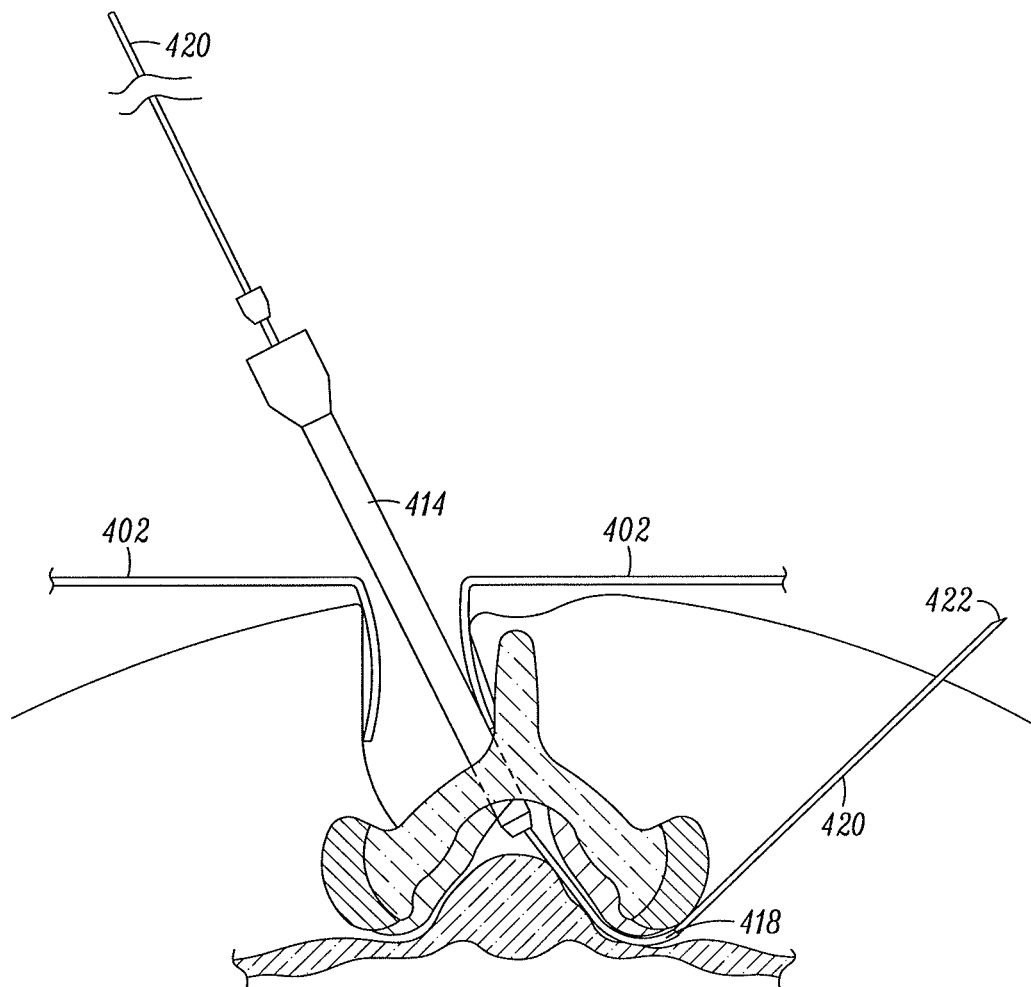


FIG. 8E

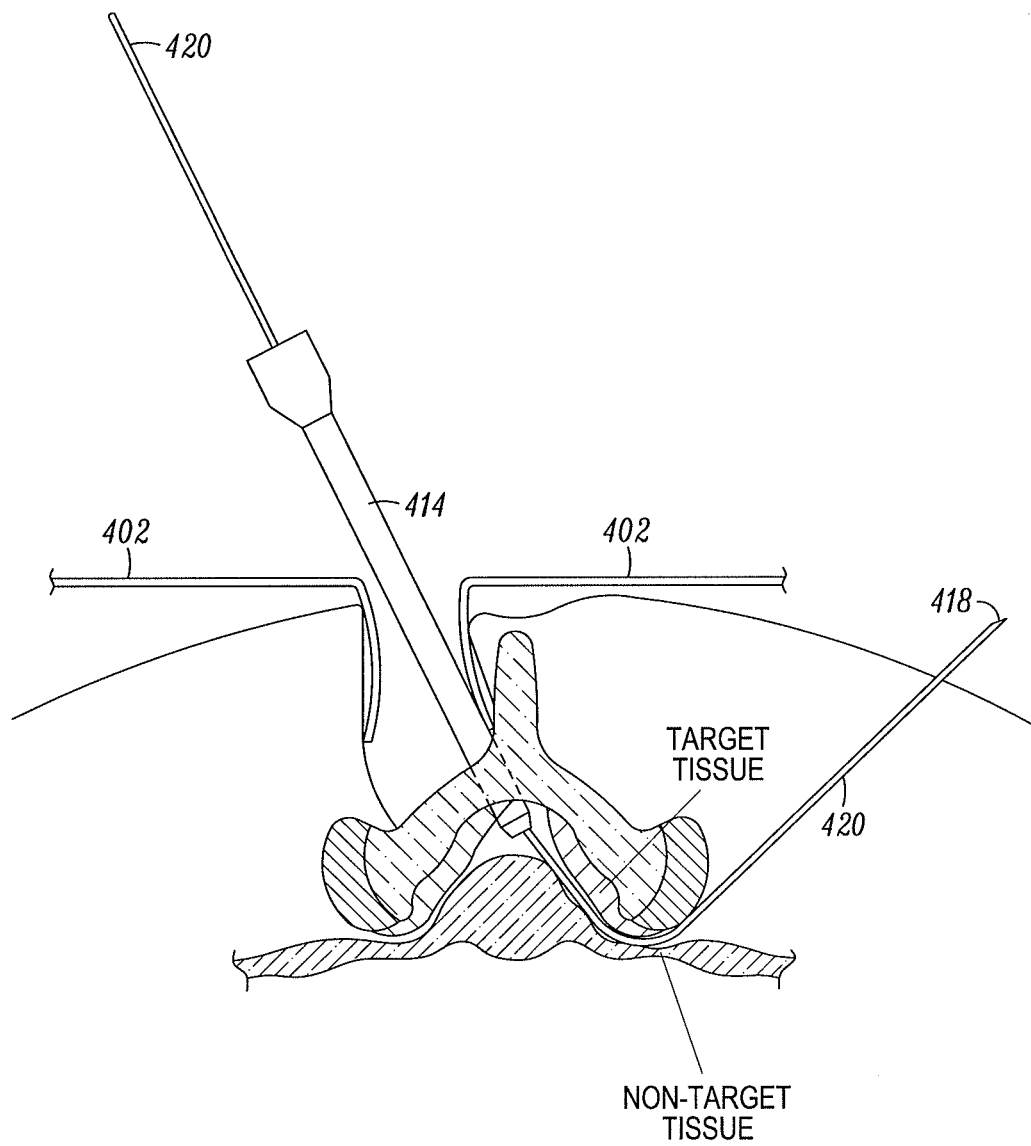


FIG. 8F

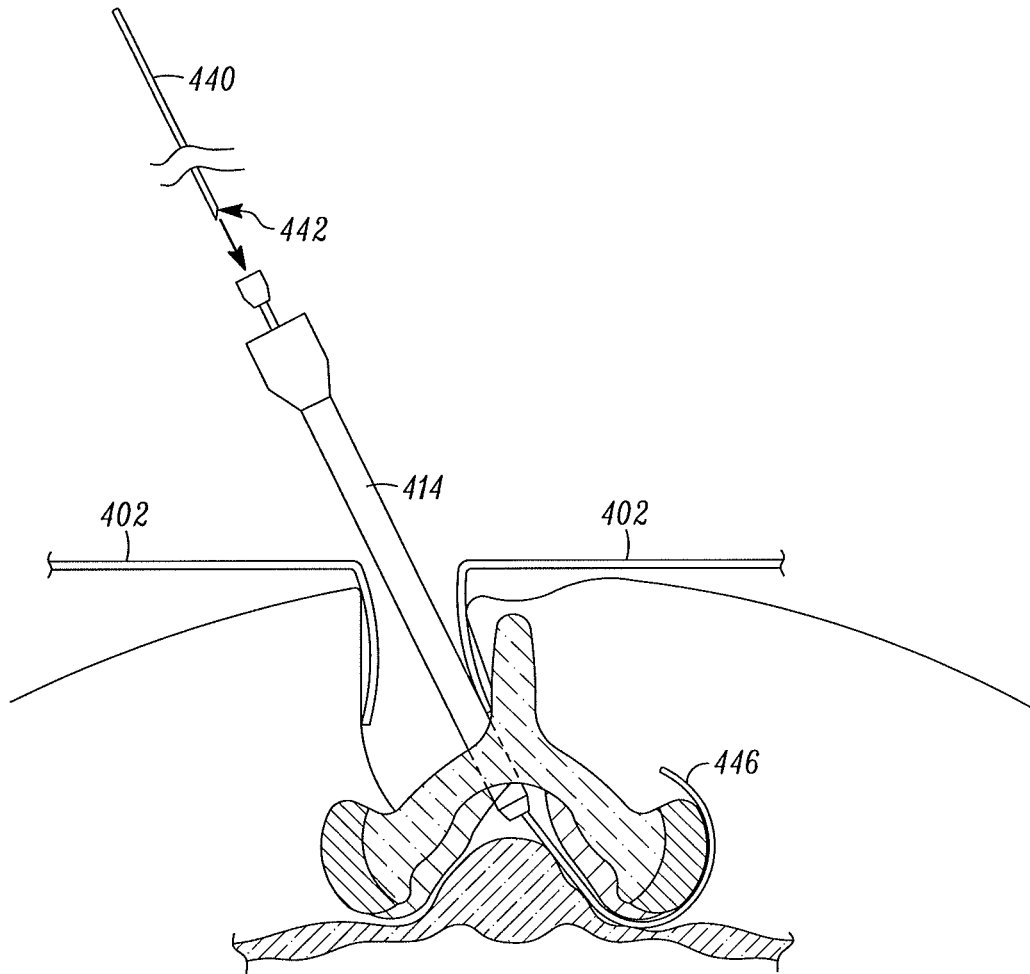


FIG. 9A

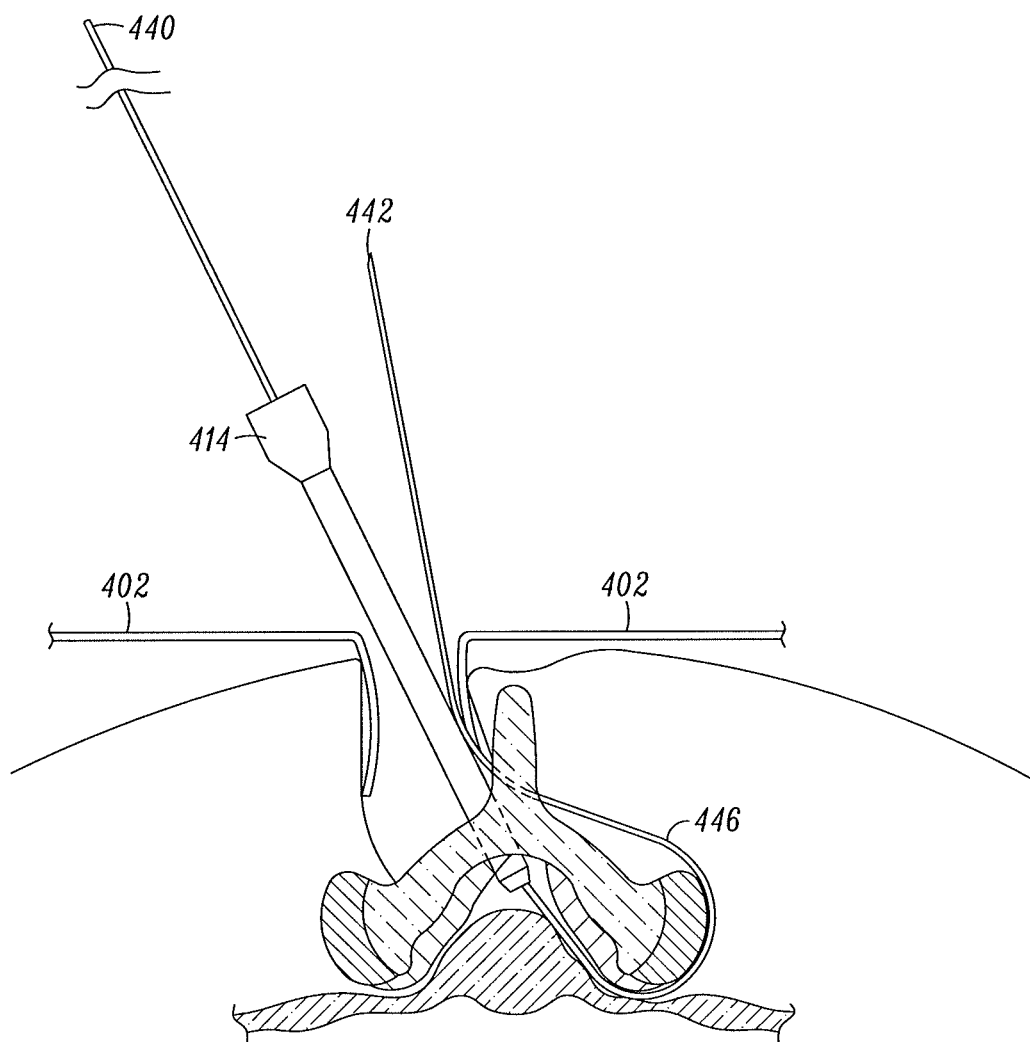


FIG. 9B

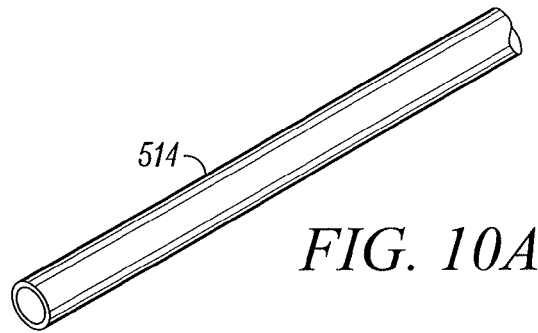


FIG. 10A

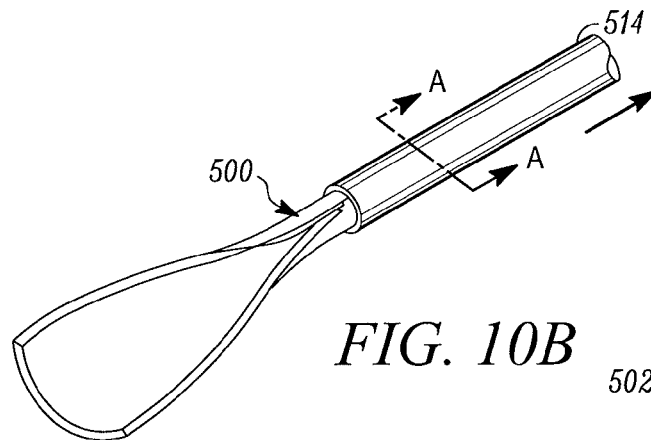
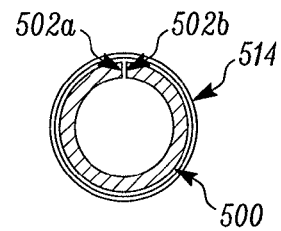


FIG. 10B



SECTION A-A

FIG. 10C

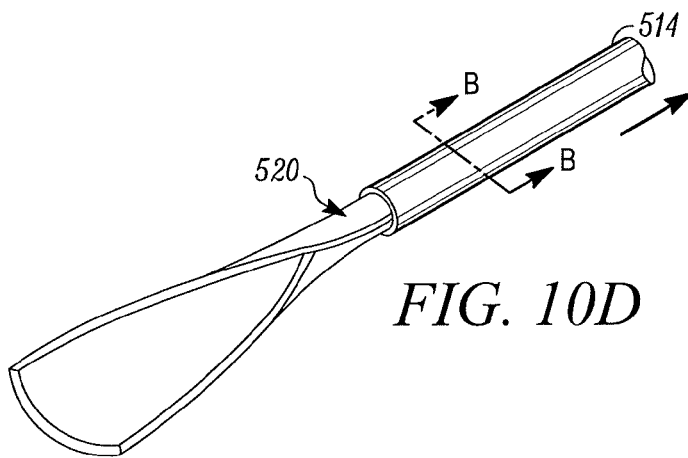
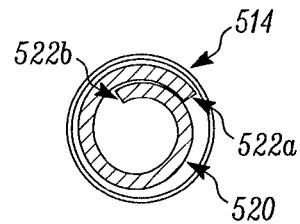


FIG. 10D



SECTION B-B

FIG. 10E

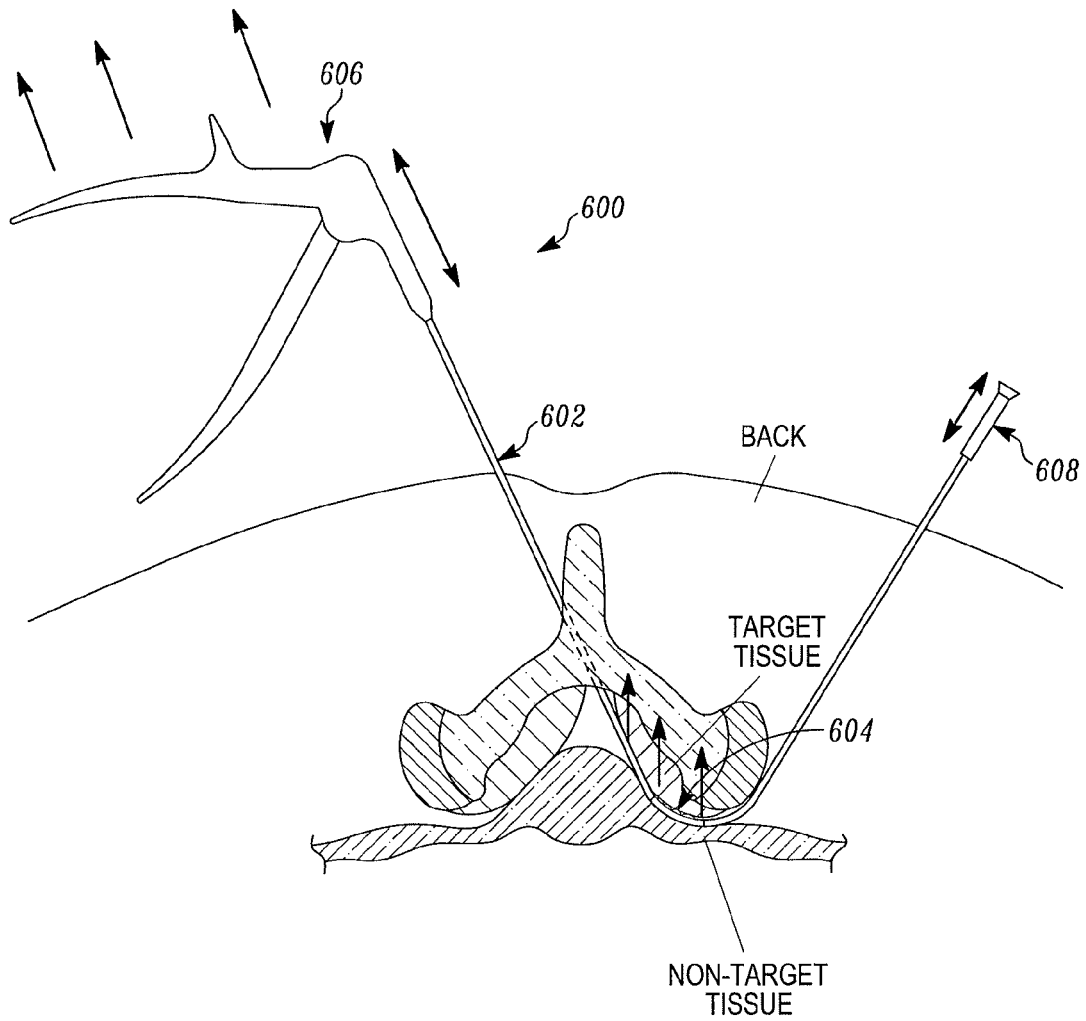


FIG. 11

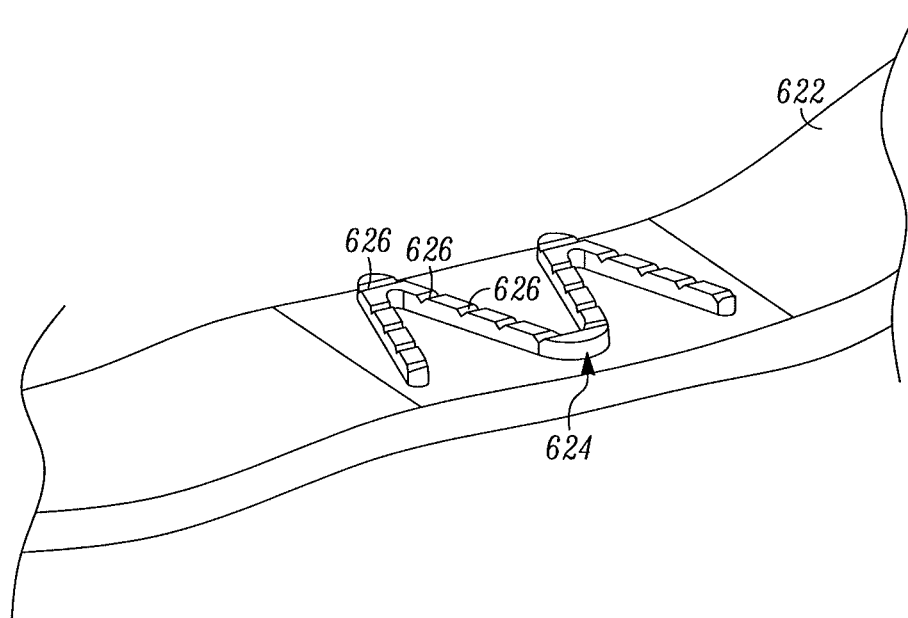


FIG. 12A

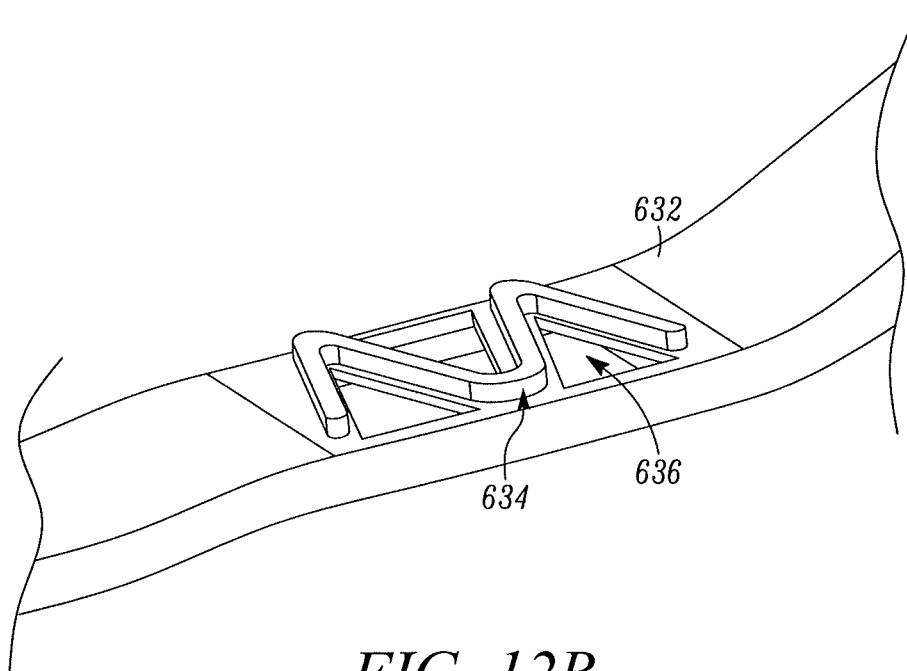


FIG. 12B

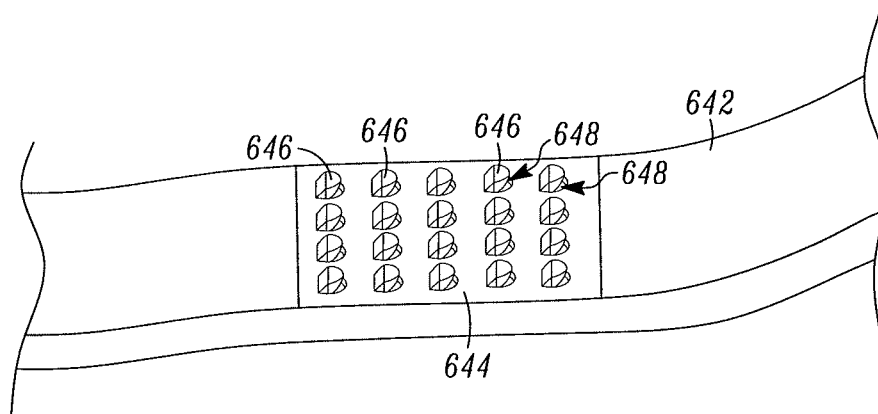


FIG. 12C

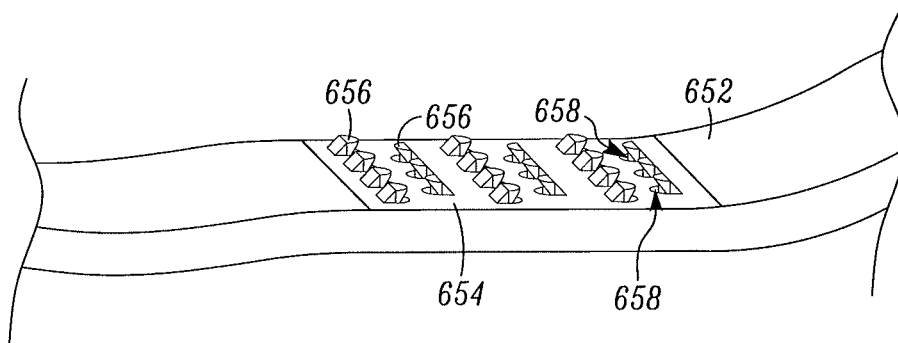


FIG. 12D

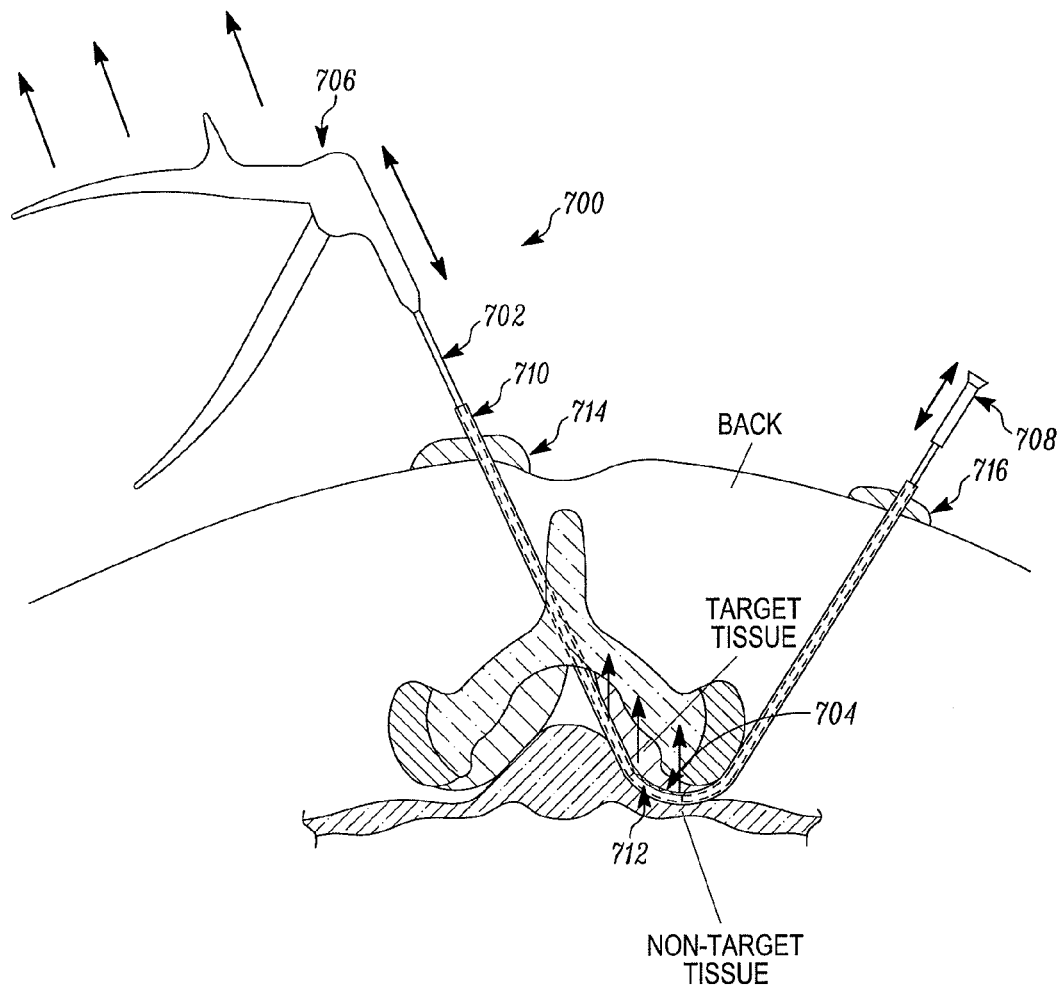


FIG. 13

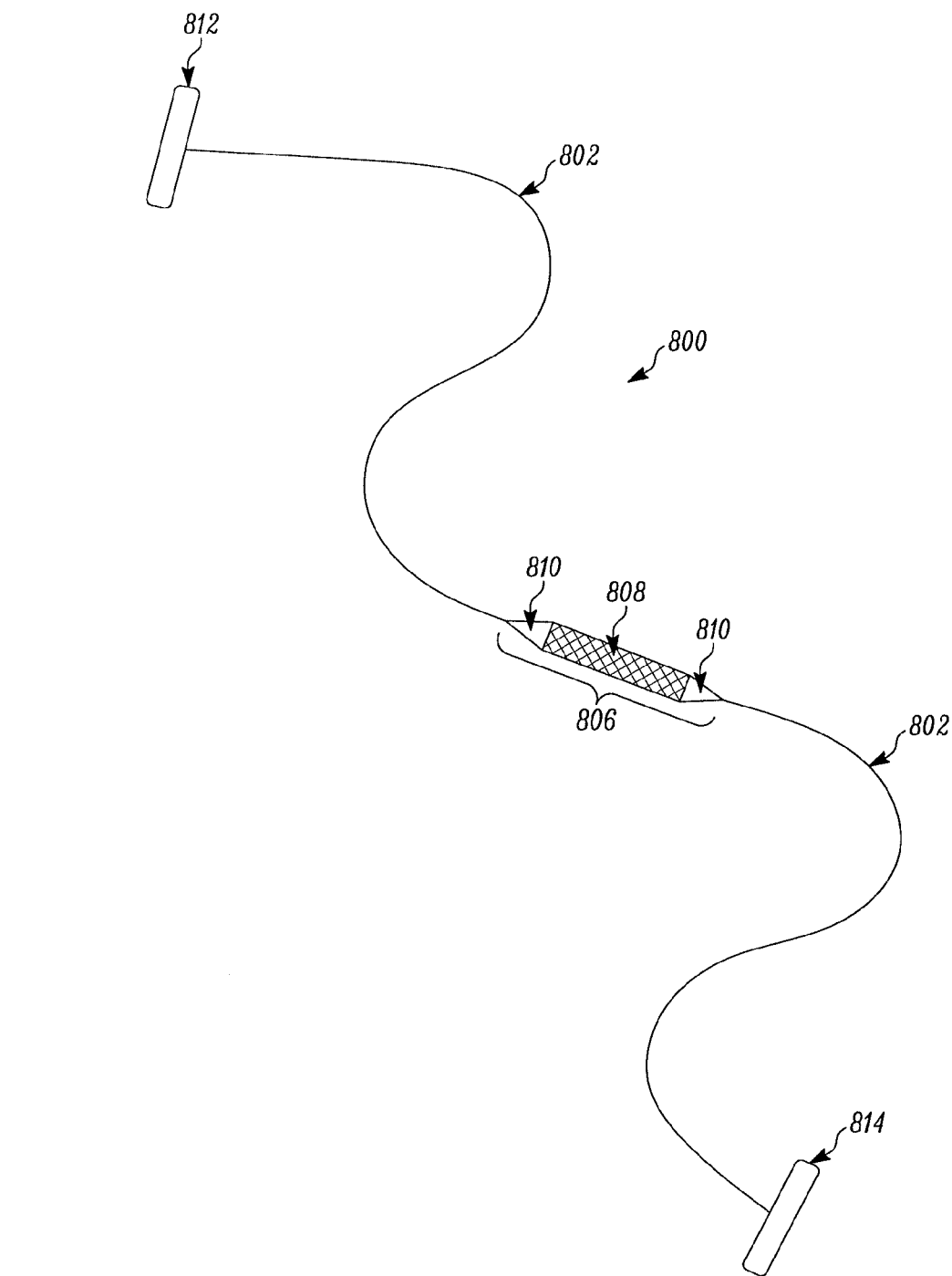


FIG. 14A

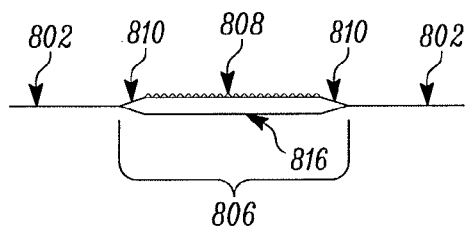


FIG. 14B

FLEXIBLE TISSUE RASP**CROSS REFERENCE TO RELATED APPLICATIONS**

The present application is a divisional of U.S. patent application Ser. No. 13/243,095, filed on Sep. 23, 2011, titled "Flexible Tissue Rasp," Publication No. US-2012-0016368-A1, which is a continuation of U.S. patent application Ser. No. 11/429,377, filed on May 4, 2006, titled "Flexible Tissue Rasp," now U.S. Pat. No. 8,048,080, which is a continuation-in-part of PCT Patent Application No. PCT/US2005/037136, filed on Oct. 15, 2005, Publication No. WO 2006/044727, which claimed the benefit of U.S. Provisional Patent Application No. 60/619,306, filed on Oct. 15, 2004, U.S. Provisional Patent Application No. 60/622,865, filed on Oct. 28, 2004, U.S. Provisional Patent Application No. 60/681,719, filed on May 16, 2005, U.S. Provisional Patent Application No. 60/681,864, filed on May 16, 2005, and U.S. Provisional Patent Application No. 60/685,190, filed on May 27, 2005, each of which is herein incorporated by reference in its entirety.

U.S. patent application Ser. No. 11/429,377 is also a continuation-in-part of U.S. patent application Ser. No. 11/375,265, filed on Mar. 13, 2006, titled "Methods and Apparatus for Tissue Modification," now U.S. Pat. No. 7,887,538, the entire disclosure of which is hereby incorporated by reference.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

The present invention relates to methods and apparatus for modifying tissue in a patient.

Many pathological conditions in the human body may be caused by enlargement, movement, displacement and/or a variety of other changes of bodily tissue, causing the tissue to press against (or "impinge on") one or more otherwise normal tissues or organs. For example, a cancerous tumor may press against an adjacent organ and adversely affect the functioning and/or the health of that organ. In other cases, bony growths (or "bone spurs"), arthritic changes in bone and/or soft tissue, redundant soft tissue, or other hypertrophic bone or soft tissue conditions may impinge on nearby nerve and/or vascular tissues and compromise functioning of one or more nerves, reduce blood flow through a blood vessel, or both. Other examples of tissues which may grow or move to press against adjacent tissues include ligaments, tendons, cysts, cartilage, scar tissue, blood vessels, adipose tissue, tumor, hematoma, and inflammatory tissue.

One specific example of a condition caused by tissue impingement is spinal stenosis. Spinal stenosis occurs when neural tissue and/or vascular tissue in the spine become impinged by one or more structures pressing against them ("neural and/or neurovascular impingement"), causing one or more symptoms. This impingement of tissue may occur in one or more of several different areas in the spine, such as in the central spinal canal (the vertical passage through which the spinal cord and cauda equina extends), the lateral recesses

of the spinal canal, or one or more intervertebral foramina (the openings through which nerve roots branching from the spinal cord pass).

For explanatory purposes, FIG. 1 is offered to show an approximate top view of a vertebra (one of the bones of the spinal column) with the cauda equina (the horsetail-shaped bundle of nerves that extends from the base of the spinal cord through the central spinal canal) shown in cross section and two nerve roots exiting the central spinal canal and extending through intervertebral foramina on either side of the vertebra. (FIG. 1 is not drawn to exact scale and is intended for exemplary purposes only. It should be emphasized here that the drawing figures appended to this application are not intended to be precisely anatomically correct and are provided for exemplary purposes to facilitate description.) The spinal cord and cauda equina run vertically along the spine through the central spinal canal, while nerve roots branch off of the spinal cord and cauda equina between adjacent vertebrae and extend through the intervertebral foramina.

One common cause of spinal stenosis is buckling and thickening of the ligamentum flavum (one of the ligaments attached to and connecting the vertebrae), as shown in FIG. 1. Buckling or thickening of the ligamentum flavum may impinge on one or more neurovascular structures, dorsal root ganglia, nerve roots and/or the spinal cord itself. Another common cause of neural and neurovascular compression within the spine is disease of one or more of the intervertebral discs (the malleable discs between adjacent vertebrae), which may lead to collapse, bulging or herniation of the disc. In FIG. 1, an intervertebral disc is shown with three solid-tipped arrows demonstrating how the disc might bulge or herniate into the central spinal canal to impinge upon the spinal cord, cauda equina and/or individual nerve roots. Other causes of neural and neurovascular impingement in the spine include: hypertrophy of one or more facet joints (also known as zygapophyseal joints, facet joints provide articulation between adjacent vertebrae—two vertebral facet superior articular processes are shown in FIG. 1); formation of osteophytes (bony growths or "bone spurs") on vertebrae; spondylolisthesis (sliding of one vertebra relative to an adjacent vertebra); and (facet joint) synovial cysts. Disc, bone, ligament or other tissue may impinge on the spinal cord, the cauda equina, branching spinal nerves and/or blood vessels in the spine to cause loss of function, ischemia (shortage of blood supply) and even permanent damage of neural or neurovascular tissue. In a patient, this may manifest as pain, impaired sensation and/or loss of strength or mobility.

In the United States, spinal stenosis occurs with an incidence of between 4% and 6% of adults aged 50 and older and is the most frequent reason cited for back surgery in patients aged 60 and older. Conservative approaches to the treatment of symptoms of spinal stenosis include systemic medications and physical therapy. Epidural steroid injections may also be utilized, but they do not provide long lasting benefits. When these approaches are inadequate, current treatment for spinal stenosis is generally limited to invasive surgical procedures to remove vertebral ligament, cartilage, bone spurs, synovial cysts, cartilage, and bone to provide increased room for neural and neurovascular tissue. The standard surgical procedure for spinal stenosis treatment includes laminectomy (complete removal of the lamina (see FIG. 1) of one or more vertebrae) or laminotomy (partial removal of the lamina), followed by removal (or "resection") of the ligamentum flavum. In addition, the surgery often includes partial or occasionally complete facetectomy (removal of all or part of one or more facet joints between vertebrae). In cases where a

bulging intervertebral disc contributes to neural impingement, disc material may be removed surgically in a discectomy procedure.

Removal of vertebral bone, as occurs in laminectomy and facetectomy, often leaves the effected area of the spine very unstable, leading to a need for an additional highly invasive fusion procedure that puts extra demands on the patient's vertebrae and limits the patient's ability to move. In a spinal fusion procedure, the vertebrae are attached together with some kind of support mechanism to prevent them from moving relative to one another and to allow adjacent vertebral bones to fuse together. Unfortunately, a surgical spine fusion results in a loss of ability to move the fused section of the back, diminishing the patient's range of motion and causing stress on the discs and facet joints of adjacent vertebral segments.

While laminectomy, facetectomy, discectomy, and spinal fusion frequently improve symptoms of neural and neurovascular impingement in the short term, these procedures are highly invasive, diminish spinal function, drastically disrupt normal anatomy, and increase long-term morbidity above levels seen in untreated patients.

Therefore, it would be desirable to have less invasive methods and devices for addressing neural and neurovascular impingement in a spine. Ideally, methods and devices for addressing impingement in spine would treat one or more target tissues while preventing unwanted effects on adjacent or nearby non-target tissues. Also ideally, such methods and devices would be minimally invasive and reduce impingement without removing significant amounts of vertebral bone, joint, or other spinal support structures, thereby avoiding the need for spinal fusion and, ideally, reducing the long-term morbidity levels resulting from currently available surgical treatments. It may also be advantageous to have less invasive methods and devices for modifying target tissues in parts of the body other than the spine while preventing modification of non-target tissues. At least some of these objectives will be met by the present invention.

2. Description of Background Art

Flexible wire saws and chain saws, such as threadwire saws (T-saws) and Gigli saws, have been used since the late 1800s to saw through or file/abrade bone and other tissue in the human body. See, for example, Brunori A et al., "Celebrating the Centennial (1894-1994): Leonardo Gigli and His Wire Saw," *J Neurosurg* 82:1086-1090, 1995. An example of one such saw is described in U.S. Pat. No. 8,250, issued to P. A. Stohlmann on Nov. 28, 1876. A description of using a T-saw to cut vertebral bone is provided in Kawahara N et al., "Recapping T-Saw Laminoplasty for Spinal Cord Tumors," *SPINE* Volume 24, Number 13, pp. 1363-1370.

A method and apparatus for treating spinal stenosis is described in PCT Patent Application Pub. No. WO 01/08571. A surgical instrument for removing cartilage from a knee cavity is described in U.S. Pat. No. 3,835,859.

SUMMARY OF THE INVENTION

In various embodiments, the present invention provides methods, apparatus and systems for modifying tissue in a patient. Generally, the methods, apparatus and systems may involve using an elongate, at least partially flexible tissue modification device having one or more tissue modification members to modify one or more target tissues. The tissue modification device may be configured such that when the tissue modification member (or members) is in a position for modifying target tissue, one or more sides, surfaces or portions of the tissue modification device configured to avoid or

prevent damage to non-target tissue will face non-target tissue. In various embodiments, during a tissue modification procedure, an anchoring force may be applied at or near either a distal portion or a proximal portion of the tissue modification device, either inside or outside the patient. Pulling or tensioning force may also be applied to the unanchored end of the device (or to both ends of the device in some embodiments), to urge the tissue modifying member(s) against target tissue. In some embodiments, tissue modifying members may be activated to modify tissue while being prevented from extending significantly beyond the target tissue in a proximal or distal direction. In some embodiments, the tissue modifying members may be generally disposed along a length of the tissue modification device that approximates a length of target tissue to be modified.

By "applying an anchoring force," it is meant that a force is applied to maintain a portion of a device, or the device as a whole, substantially stable or motion-free. Applying an anchoring force is, therefore, not limited to preventing all movement of a device, and in fact, a device to which an anchoring force is applied may actually move in one or more directions in some embodiments. In other embodiments, an anchoring force is applied to maintain a portion of a device substantially stable, while another portion of the device is allowed to move more freely. As will be described in further detail below, applying an anchoring force in one embodiment involves a user of a device grasping the device at or near one of its ends. In other embodiments, devices may use one or more anchoring members to apply an anchoring force. In a number of embodiments, an anchoring force may be applied with or against one or more tissues of a patient's body, and the tissue(s) may often move even as they apply (or help apply) the force. Thus, again, applying an anchoring force to a device does not necessarily mean that all motion of the device is eliminated. Of course, in some embodiments, it may be possible and desirable to eliminate all movement or substantially all movement of a device (or portion of a device), and in some embodiments anchoring force may be used to do so.

Methods, apparatus and systems of aspects of the present invention generally provide for tissue modification while preventing unwanted modification of, or damage to, surrounding tissues. Tensioning the tissue modification device by applying anchoring force at or near one end and applying tensioning or pulling force at or near the opposite end may enhance the ability of tissue modification members of the device to work effectively within a limited treatment space. Applying tensioning force to a predominantly flexible device may also allow the device to have a relatively small profile, thus facilitating its use in less invasive procedures and in other procedures in which alternative approaches to target tissue may be desired.

In some embodiments, the described methods, apparatus and systems may be used to modify tissue in a spine, such as for treating neural impingement, neurovascular impingement and/or spinal stenosis. In alternative embodiments, target tissues in other parts of the body may be modified.

In one aspect of the present invention, a method for modifying tissue in a spine of a patient to treat or alleviate at least one of foraminal spinal stenosis and lateral recess spinal stenosis may include: advancing at least a distal portion of an elongate, at least partially flexible, tissue modification device into an epidural space of the patient's spine and between target tissue and non-target tissue in the spine; positioning the tissue modification device so that at least one abrasive surface of the device faces target tissue and at least one non-abrasive surface faces non-target tissue; applying tensioning force at or near the distal portion of the tissue modification device by

5

pulling on distal tensioning means coupled with the tissue modification device at or near the distal portion; applying tensioning force at or near a proximal portion of the tissue modification device by separately pulling on proximal tensioning means coupled with the tissue modification device at or near the proximal portion and not directly connected to the distal tensioning means, to urge the at least one abrasive surface against the target tissue; and translating the tissue modification device back and forth while maintaining at least some tensioning force to abrade at least a portion of the target tissue with the at least one abrasive surface, while preventing unwanted damage to the non-target tissue with the at least one non-abrasive surface.

By "not directly connected to the distal tensioning means," it is meant that the proximal and distal tensioning means are not connected to one another by a common handle or other connecting device or mechanism. In other words, although the proximal and distal tensioning means may be coupled with the tissue modification device at or near the proximal and distal ends of the device, respectively, and thus the tensioning means may be connected to one another through the device, they are not connected to one another by any other means.

In another aspect of the present invention, a method for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis may involve: advancing an elongate, at least partially flexible, shield member into an epidural space of the patient's spine and between target tissue and non-target tissue in the spine; exposing an abrasive surface of an elongate, at least partially flexible tissue modification member through an opening on the shield member; applying tensioning force at or near a distal portion of at least one of the shield member and the tissue modification member by pulling on distal tensioning means coupled with the distal portion of at least one of the shield member and the tissue modification member; applying tensioning force at or near a proximal portion of at least one of the shield member and the tissue modification member by separately pulling on proximal tensioning means coupled with the proximal portion of at least one of the shield member and the tissue modification member and not directly connected to the distal tensioning means, to urge the at least one abrasive surface against the target tissue; and translating the tissue modification device back and forth while maintaining at least some tensioning force to abrade at least a portion of the target tissue with the abrasive surface, while preventing unwanted damage to the non-target tissue with the shield member, wherein abrading the target tissue enlarges at least one opening in the spine without completely cutting through bone.

In another aspect of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis may include: an elongate, at least partially flexible body having a proximal portion and a distal portion; at least one abrasive surface disposed along a portion of one side of the elongate body; at least one non-abrasive surface located adjacent the at least one abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue; at least one proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and at least one distal tensioning member, coupled with the elongate body at or near the distal portion and not directly connected to the proximal tensioning member, for facilitating application of tensioning force to, and translation of, the elongate body.

In another aspect of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis may include: an elongate, at least partially

6

flexible shield member having a proximal portion, a distal portion and at least one opening along its length; an elongate, at least partially flexible tissue modification member disposed at least partly within the shield member, the tissue modification member having a proximal portion, a distal portion, and at least one abrasive surface; at least one proximal tensioning member at or near the proximal portion of at least one of the shield member and the tissue modification member for facilitating application of tensioning force in a first direction; and at least one distal tensioning member at or near the distal portion of at least one of the shield member and the tissue modification member and not directly connected to the proximal tensioning member, for facilitating application of tensioning force in a second direction.

These and other aspects and embodiments are described more fully below in the Detailed Description, with reference to the attached Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is cross-sectional view of a spine, showing a top view of a lumbar vertebra, a cross-sectional view of the cauda equina, and two exiting nerve roots;

FIG. 2 is a cross-sectional view of a portion of a patient's back and spine, showing part of a vertebra and apparatus in place for modifying tissue according to one embodiment of the present invention;

FIG. 3A is a perspective view of a tissue modification device according to one embodiment of the present invention;

FIG. 3B is a perspective view of a portion of the tissue modification device of FIG. 3A;

FIG. 3C is a top view of the portion shown in FIG. 3B;

FIG. 3D is a side view of the portion shown in FIGS. 3B and 3C;

FIGS. 3E and 3F are cross-sectional views of a portion of the tissue modification device taken through lines A-A and B-B, respectively, shown in FIG. 3C;

FIG. 3G is a perspective view of a portion of the tissue modification device of FIGS. 3B-3F, shown with a blade of the device in a closed position according to one embodiment of the present invention;

FIG. 3H is a top view of the portion shown in FIG. 3G;

FIG. 3I is a side view of the portion shown in FIGS. 3G and 3H;

FIG. 4A is a perspective view of a tissue modification device according to one embodiment of the present invention;

FIG. 4B is a perspective view of a portion of the tissue modification device of FIG. 4A;

FIG. 4C is a close-up, perspective view of a portion of the tissue modification device of FIGS. 4A and 4B, showing a tissue modifying member according to one embodiment of the present invention;

FIGS. 5A-5D are cross-sectional views of a spine and demonstrate a method for using a tissue modification device according to one embodiment of the present invention;

FIG. 6A is a cross-sectional view of a portion of a patient's spine and back, with apparatus for modifying tissue in position for modifying spinal tissue and with a distal portion of the apparatus anchored outside the patient according to one embodiment of the present invention;

FIG. 6B is a cross-sectional view of a portion of a patient's spine and back, with apparatus for modifying tissue in position for modifying spinal tissue and with a distal portion of the apparatus anchored inside the patient according to one embodiment of the present invention;

FIGS. 7A-7S are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for intro-

ducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to one embodiment of the present invention;

FIGS. 8A-8F are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for introducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to an alternative embodiment of the present invention;

FIGS. 9A-9B are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for introducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to an alternative embodiment of the present invention;

FIG. 10A is a perspective view of a distal portion of an introducer sheath according to one embodiment of the present invention;

FIGS. 10B and 10C are perspective and cross-sectional views, respectively, of a tissue shield device according to one embodiment of the present invention; and

FIGS. 10D and 10E are perspective and cross-sectional views, respectively, of a tissue shield device according to an alternative embodiment of the present invention.

FIG. 11 is a side view of a tissue modification rasp device, shown with a cross-sectional view of a spine according to one embodiment of the present invention.

FIGS. 12A-12D are perspective views of various abrasive, tissue modifying portions of tissue modification rasp devices, according to various embodiments of the present invention.

FIG. 13 is a side view of a tissue modification rasp device including a barrier member according to one embodiment of the present invention.

FIGS. 14A and 14B are perspective and partial side views, respectively, of a tissue modification rasp device according to an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Methods, apparatus and systems for modifying tissue in a patient are provided. Although the following description and accompanying drawing figures generally focus on tissue modification in spine, in various alternative embodiments any of a number of tissues in any of a number of anatomical locations in a patient may be modified.

Referring to FIG. 2, in one embodiment a tissue modification device 102 may include an elongate body 108 having a proximal portion 107 and a distal portion 109, a handle 104 with an actuator 106 coupled with proximal portion 107, one or more tissue modifying members 110, and one or more protective surfaces 112. In various embodiments, some of which are described further below, modification device 102 may be introduced into an area for performing a treatment, such as a spine, using any of a number of different introduction methods, devices and systems 100. In FIG. 2, for example, modification device 102 extends through an introducer device 114 placed through a first incision 240 on the patient's back and into the central spinal canal. Modification device 102 is advanced along a guide member 116, which extends through introducer member 114, through the intervertebral foramen between two adjacent vertebrae (only part of one vertebra is shown in FIG. 2), and out a second (or "distal") incision 242 on the back. In some embodiments, as shown, guide member has a beveled distal tip 117 for facilitating advancement of guide member 116 through tissue.

Generally, tissue modification device 102 may be advanced to a position in the spine such that tissue modifying member 110 faces target tissue to be modified, such as buckled, thickened or otherwise impinging ligamentum flavum

tissue as shown in FIG. 2. Modification device 102 is configured such that when tissue modifying member 110 faces the target tissue, protective surface(s) 112 face non-target tissue. Protective surface 112 may be simply a length of elongate body 108 or may have one or more protective features, such as a widened diameter, protective or lubricious coating, extendable barrier, drug-eluting coating or ports, or the like. In some instances, protective surface(s) 112 may act as "non-tissue-modifying" surfaces, in that they may not substantially modify the non-target tissue. In alternative embodiments, protective surface(s) 112 may affect non-target tissue by protecting it in some active way, such as by administering one or more protective drugs, applying one or more forms of energy, providing a physical barrier, or the like.

In some embodiments, once tissue modification device 102 is positioned such that tissue modifying member 110 faces target tissue and protective surface 112 faces non-target tissue, an anchoring force may be applied at or near distal portion 109 of elongate body 108, either inside or outside the patient's body. A tensioning force may also be applied at or near proximal portion 107 of elongate body 108, such as by pulling on handle 104 (one-directional arrows), and actuator 106 may be used (two-headed arrow) to activate tissue modifying member(s) 110 to modify target tissue. In the example shown, anchoring force is applied near distal portion 109 by a user's hand 244, and handle 104 is pulled proximally (arrows) to apply tensioning force. In an alternative embodiment, hand 244 may grasp guide member 116 at or near its distal portion 117 and thus apply anchoring force to it, thus also applying anchoring force to elongate body 108. In one variation of such an embodiment, elongate body 108 or handle 104 may optionally be adjustably clamped to guide member 116 to further enhance or facilitate application of anchoring force to elongate body 108. Tissue modification via tissue modifying members 110 may include cutting, ablating, dissecting, repairing, reducing blood flow in, shrinking, shaving, burring, biting, remodeling, biopsying, debriding, lysing, debulking, sanding, filing, planing, heating, cooling, vaporizing, delivering a drug to, and/or retracting the target tissue. Once tissue has been modified, tissue modification device 102 and any introducer devices 114, guide members 116 or other devices may be removed from the patient.

In various embodiments of the apparatus, tissue modifying member(s) 110 may be disposed along any suitable length of body 108. In one embodiment, for example, such as an embodiment of the device to be used in a spinal treatment, tissue modifying members 110 may be disposed along a length of the device measuring no longer than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. In various embodiments, tissue modifying member(s) 110 may include a rongeur, a curette, a scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, a pressurized water jet, a drug dispensing element, a needle, a needle electrode, or some combination thereof. In various embodiments, all tissue modifying members 110 may be mobile relative to the elongate body, all may be static, or some may be mobile and some may be static. These and other aspects and embodiments are described further below.

Turning now to FIG. 3A-3I, more detailed figures of one embodiment of tissue modification device 102 are shown. Referring to FIG. 3A, tissue modification device 102 may

include elongate body **108** having proximal portion **107** and distal portion **109**, a window **111** disposed along elongate body **108**, two tissue modifying blades **110** exposed through window **111**, and handle **104** with actuator **106** coupled with proximal portion **107**. In the embodiment shown, the tissue modifying members comprise blades **110**, although in alternative embodiments other tissue modifying members may be added or substituted.

In various embodiments, elongate body **108** may have any number of dimensions, shapes, profiles and amounts of flexibility. For example, distal portion **109** is shown having a curved shape to demonstrate that at least a portion of elongate body **108** may be flexible. In various embodiments, elongate body **108** may have one or more of a round, ovoid, ellipsoid, flat, cambered flat, rectangular, square, triangular, symmetric or asymmetric cross-sectional shape. As shown in FIGS. **3C** and **3D**, in the pictured embodiment, elongate body **108** has a relatively flat configuration, which may facilitate placement of body **108** between target and non-target tissues. Distal portion **109** of body **108** may be tapered, to facilitate its passage into or through narrow spaces as well as through small incisions on a patient's skin. Body **108** may also include a slightly widened portion around the area of window **111** and blades. In one embodiment, such as an embodiment used for modifying tissue in a spine, body **108** may have a small profile, such as having a height of not more than 10 mm at any point along its length and a width of not more than 20 mm at any point along its length, or more preferably a height not more than 5 mm at any point along its length and a width of not more than 10 mm at any point along its length, or even more preferably a height not more than 2 mm at any point along its length and a width of not more than 4 mm at any point along its length. Body **108** may be long enough to extend through a first incision on a patient, between target and non-target tissue, and out a second incision on a patient. Alternatively, body **108** may be long enough to extend through a first incision, between the target and non-target tissue, and to an anchoring location within the patient. In another alternative embodiment, body **108** may be long enough to extend through a first incision, between the target and non-target tissue, to a location nearby but distal to the target tissue within the patient, with some portion of tissue modification device **102** anchored to guide member **116**. In some embodiments, elongate body **108** includes at least one feature for allowing passage of the body over a guidewire or other guide member or to allow passage of one or more guide members over or through body **108**. For example, in various embodiments body **108** may include one or more guidewire lumens, rails, tracks, lengthwise impressions or some combination thereof.

In one embodiment, elongate body **108** is predominantly flexible along its length and comprises any suitable flexible material, such as thin, flexible metals, plastics, fabrics or the like. In some embodiments, it may be advantageous to include one or more rigid sections in elongate body **108**, such as to impart pushability to a portion of body **108** or to facilitate application of force to tissue modification members **110** without causing unwanted bending or kinking of elongate body **108**. In such embodiments, rigidity may be conferred by using additional materials in body **108** or by making the rigid portions thicker or wider or of a different shape.

Handle **104** may have any suitable configuration according to various embodiments. Similarly, actuator **106** may include any of a number of actuation devices in various embodiments. In the embodiment shown in FIG. **3A**, actuator **106** comprises a trigger or moving handle portion, which is grasped by a user and pulled or squeezed toward handle **104** to bring blades **110**

together to cut tissue. In an alternative embodiment, actuator **106** instead may include a switch or button for activating a radiofrequency surgical ablation tissue modifying member. In yet another embodiment, actuator **106** may include a combination trigger and switch, one or more pull wires, any suitable form of lever and/or some combination thereof.

FIGS. **3B-3D** show in greater detail a portion of tissue modification device **102**. In these figures, window **111** and blades **110** are more clearly seen. In one embodiment, at least a portion of elongate body **108** and blades **110** may have a slightly curved configuration. In alternative embodiments, at least a portion of elongate body **108** and blades **110** may be flat. In other alternative embodiments, tissue modification members such as blades **110** may be proud to elongate body **108**.

Blades **110** include a distal **110a** and a proximal blade **110b** that reside at the distal and proximal edges, respectively, of window **111** of elongate body **108**. Window **111** of body **108** may accommodate both soft and hard tissue when the device is forcibly applied to the surface of a target tissue site. The top view of the distal portion of elongate body **108**, shown in FIG. **3C**, depicts the angled edges of distal blade **110a** and proximal blade **110b**, which facilitate shearing of target tissue. In alternative embodiments, blades **110** may have any of a number of alternative shapes and configurations. The distal portion of body **108** may have a very low profile (height compared to width), as shown in side view FIG. **3D**, where only blades **110** protrude from the top surface of the elongate body **108**. In one embodiment, also as shown in FIG. **3D**, a guidewire tube **120** (or lumen) may extend from (or be coupled with) a lower surface of elongate body **108**. The lower surface of elongate body **108** is an example of a protective or non-tissue-modifying surface.

In one embodiment, distal blade **110a** is coupled with two pull-wires **118**, as seen in FIGS. **3C**, **3E** and **3F**. Pull-wires **118** coupled to and translated by actuator **106** on handle **104** may be used to drive distal blade **110a** proximally to contact the cutting edge of proximal blade **110b**, thus cutting tissue. Other alternative mechanisms for driving blades **110**, such as gears, ribbons or belts, magnets, electrically powered, shape memory alloy, electro magnetic solenoids and/or the like, coupled to suitable actuators, may be used in alternative embodiments. As mentioned, in one embodiment distal blade **110a** and/or proximal blade **110b** may have an outwardly curvilinear shape along its cutting edge. Alternatively, distal blade **110a** may have a different blade shape, including flat, rectilinear, v-shaped, and inwardly curvilinear (concave vs. convex). The cutting edge of either blade **110** may have a sharp edge formed by a simple bevel or chamfer. Alternatively or in addition, a cutting edge may have tooth-like elements that interlock with a cutting edge of an opposing blade, or may have corrugated ridges, serrations, rasp-like features, or the like. In various embodiments, both blades **110** may be of equal sharpness, or alternatively one blade **110** may be sharp and the other substantially flat to provide a surface against which the sharp blade **110** may cut. Alternately or in addition, both cutting edges may be equally hard, or a first cutting edge may be harder than a second, the latter of which deflects under force from the first harder edge to facilitate shearing of the target tissue.

FIGS. **3E** and **3F** show cross-sectional views through elongate body at lines A-A and B-B, respectively, of FIG. **3C**. In some embodiments, all or a portion of elongate body **108**, such as the lower surface shown in FIG. **3E**, may include a lubricious surface for facilitating manipulation of the tool in the surgical space and at the anatomical site. The lubricious lower surface also provides a barrier between blades **110** and

11

non-target tissue in the surgical space. The lower surface may include a guide member lumen **120** to accommodate a guidewire or other access device or rail. FIG. 3E shows distal blade **110** coupled with pull wires **118**. FIG. 3F shows proximal blade **110b**, which is not coupled with pull wires **118** but rather fixed to body **108**. In various alternative embodiments, proximal blade **110b** may be movable distally while distal blade **110a** is static, both blades may be moved toward one another, or a different number of blades may be used, such as one blade drawn toward a backstop or more than two blades, one or more of which may be mobile. In various alternative embodiments, guide member lumen **120** may be accommodated on a side surface or more centrally within elongate body **108**. In further alternative embodiments, the one or more guide member lumens **120** may comprise one or more various cross sectional shapes, for example substantially round, substantially oval, or substantially rectabular, to accommodate alternative guide members, for example flat or rectangular guidewires, needles or rails. In still other alternative embodiments guide member lumen **120** may be adjustably coupled with the elongate body **108** to enable manipulation of the location of the elongate body **108** and therefore the tissue modifying members **110** relative to the guiding member.

Referring now to FIGS. 3G-3I, blades **110** are shown in their closed position. In one embodiment, when distal blade **110a** is drawn proximally to cut tissue, at least some of the cut tissue is captured in a hollow interior portion of elongate body **108**. Various embodiments may further include a cover, a cut tissue housing portion and/or the like for collecting cut tissue and/or other tissue debris. Such collected tissue and debris may then be removed from the patient during or after a tissue modification procedure. During a given tissue modification procedure, distal blade **110a** may be drawn proximally to cut tissue, allowed to retract distally, and drawn proximally again to further cut tissue as many times as desired to achieve a desired amount of tissue cutting.

Blades **110** may be made from any suitable metal, polymer, ceramic, or combination thereof. Suitable metals, for example, may include but are not limited to stainless steel, nickel-titanium alloy, tungsten carbide alloy, or cobalt-chromium alloy, for example, Elgiloy® (Elgin Specialty Metals, Elgin, Ill., USA), Conichrome® (Carpenter Technology, Reading, Pa., USA), or Phynox® (Imphy SA, Paris, France). In some embodiments, materials for the blades or for portions or coatings of the blades may be chosen for their electrically conductive or thermally resistive properties. Suitable polymers include but are not limited to nylon, polyester, Dacron®, polyethylene, acetal, Delrin® (DuPont, Wilmington, Del.), polycarbonate, nylon, polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). In some embodiments, polymers may be glass-filled to add strength and stiffness. Ceramics may include but are not limited to aluminas, zirconias, and carbides. In various embodiments, blades **110** may be manufactured using metal injection molding (MIM), CNC machining, injection molding, grinding and/or the like. Pull wires **118** be made from metal or polymer and may have circular, oval, rectangular, square or braided cross-sections. In some embodiments, a diameter of a pull wire **118** may range from about 0.001"-0.050", and more preferably from about 0.010"-0.020".

Depending on the tissue to be treated or modified, activating blades **110** (or other tissue modifying members in alternative embodiments) may cause them to modify target tissue along an area having any of a number of suitable lengths. In use, it may also be advantageous to limit the extent of action of blades **110** or other tissue modifying members to a desired length of tissue, thus not allowing blades **110** to affect tissue

12

beyond that length. In so limiting the effect of blades, unwanted modification of, or damage to, surrounding tissues and structures may be limited or even eliminated. In one embodiment, for example, where the tissue modification device is used to modify tissue in a spine, blades **110** may operate along a length of target tissue of no more than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. Of course, in other parts of the body and to address other tissues, different tissue modification devices may be used and tissue modifying members may have many different lengths of activity. In one embodiment, to facilitate proper location of tissue modifying members, such as blades **110**, relative to target tissue, the tissue modifying members and/or the elongate body and/or one or more additional features intended for just such a purpose may be composed of a material readily identifiable via x-ray, fluoroscopic, magnetic resonance or ultrasound imaging techniques.

In various embodiments, a number of different techniques may be used to prevent blades **110** (or other tissue modifying members) from extending significantly beyond the target tissue. In one embodiment, for example, preventing blades **110** from extending significantly beyond the target tissue involves holding tissue modification device **102** as a whole predominantly stable to prevent device **102** from translating in a direction toward its proximal portion or toward its distal portion while activating blades **110**. Holding device **102** stable is achieved by anchoring one end of the device and applying tensioning force at or near the other end, as described further below.

In the embodiment shown in FIGS. 3A-3I, pull wires **118** are retracted proximally by squeezing actuator **106** proximally. In an alternative embodiment, squeezing actuator **106** may cause both blades **110** to translate inward so that they meet approximately in the middle of window **111**. In a further embodiment, distal blade **110a** may be returned to its starting position by a pulling force generated from the distal end of device **102**, for example by using a distal actuator that is attached to distal wires, or by pulling on the distal guide member which is attached to distal blade **110a**. In yet another alternative embodiment, proximal blade **110b** may be moved to cut by a pulling force generated from the distal end of device **102**, for example by using a distal actuator that is attached to distal wires, or by pulling on the distal guide member which is attached to proximal blade **110b**. In yet another embodiment, squeezing actuator **106** may cause proximal blade **110b** to move distally while distal blade **110a** stays fixed. In other alternative embodiments, one or more blades **110** may move side-to-side, one or more blades **110** may pop, slide or bow up out of window **111** when activated, or one or more blades **110** may expand through window. In another embodiment, one or more blades **110** and/or other tissue modifying members of device **102** may be powered devices configured to cut, shave, grind, abrade and/or resect target tissue. In other embodiments, one or more blades may be coupled with an energy transmission device, such as a radiofrequency (RF) or thermal resistive device, to provide energy to blade(s) **110** for cutting, ablating, shrinking, dissecting, coagulating or heating and thus enhancing tissue modification. In another embodiment, a rasp or file may be used in conjunction with or coupled with one or more blades. In any of these embodiments, use of actuator **106** and one or more moving blades **110** provides for tissue modification with relatively little overall translation or other movement of tissue modification device **102**. Thus, target tissue may be modified without extending blades **110** or other tissue modification members significantly beyond an area of target tissue to be treated.

13

Referring now to FIGS. 4A-4C, in an alternative embodiment, a tissue modification device 202 may include an elongate body 208 having a proximal portion and a distal portion 209, a handle 204 and actuator 206 coupled with proximal portion, and a window 211 and tissue modifying member 210 disposed near distal portion 209. As seen more clearly in FIGS. 4B and 4C, in the embodiment shown, tissue modifying member 210 comprises an RF electrode wire loop. Wire loop 210 may comprise any suitable RF electrode, such as those commonly used and known in the electrosurgical arts, and may be powered by an internal or external RF generator, such as the RF generators provided by Gyrus Medical, Inc. (Maple Grove, Minn.). Any of a number of different ranges of radio frequency may be used, according to various embodiments. For example, some embodiments may use RF energy in a range of between about 70 hertz and about 5 megahertz. In some embodiments, the power range for RF energy may be between about 0.5 Watts and about 200 Watts. Additionally, in various embodiments, RF current may be delivered directly into conductive tissue or may be delivered to a conductive medium, such as saline or Lactate Ringers solution, which may in some embodiments be heated or vaporized or converted to plasma that in turn modifies target tissue. Distal portion 209 includes a tapered tip, similar to that described above, to facilitate passage of elongate body 208 into narrow anatomical sites. Handle 204 and actuator 206 are similar to those described above, although in the embodiment of FIGS. 4A-4C, actuator 206 may be used to change the diameter of the wire loop 210. Using actuator 206, wire loop 210 may be caused to extend out of window 211, expand, retract, translate and/or the like. Some embodiments may optionally include a second actuator (not shown), such as a foot switch for activating an RF generator to delivery RF current to an electrode.

Elongate body 208 may be fabricated from any suitable material and have any of a number of configurations. In one embodiment, body 208 comprises a metal tube with a full-thickness slit (to unfold the tube into a flat form—not shown) or stiffening element (not shown). The split tube provides for a simple manufacturing process as well as a conductive pathway for bi-polar RF operation. The tube may include a waist region 220.

Referring to FIG. 4C, insulators 222 may be disposed around a portion of wire loop 210 so that only a desired portion of wire loop 210 may transfer RF current into the tissue for tissue modifying capability. Wire loop 210, covered with insulators 222 may extend proximally into support tubes 218. In various alternative embodiments, an electrode tissue modifying member (of which wire loop 210 is but one example) may be bipolar or monopolar. For example, as shown in FIG. 4C, a sleeve 224 housed toward the distal portion of window 211 may act as a return electrode for wire loop 210 in a bipolar device. Wire loop electrodes 210 may be made from various conductive metals such as stainless steel alloys, nickel titanium alloys, titanium alloys, tungsten alloys and the like. Insulators 222 may be made from a thermally and electrically stable polymer, such as polyimide, polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), polyamide-imide, or the like, and may optionally be fiber reinforced or contain a braid for additional stiffness and strength. In alternative embodiments, insulators 222 may be composed of a ceramic-based material.

In one embodiment, wire loop 210 may be housed within elongate body 208 during delivery of tissue modification device 202 into a patient, and then caused to extend up out of window 211, relative to the rest of body 208, to remove tissue. Wire loop 210 may also be flexible so that it may pop or bow up out of window 211 and may deflect when it encounters

14

hard tissue surfaces. Wire loop 210 may have any of a number of shapes, such as curved, flat, spiral or ridged. Wire loop 210 may have a diameter similar to the width of body 208, while in alternative embodiments it may expand when extended out of window 211 to have a smaller or larger diameter than that of body 208. Pull wires (not shown) may be retracted proximally, in a manner similar to that described above, in order to collapse wire loop 210, decrease the diameter and lower the profile of the wire loop 210, and/or pull wire loop 210 proximally to remove tissue or be housed within body 208. The low profile of the collapsed wire loop 210, facilitates insertion and removal of tissue modification device 202 prior to and after tissue modification. As the wire loop 210 diameter is reduced, support tubes 218 deflect toward the center of elongate body 208.

In an alternative embodiment (not shown), tissue modification device 202 may include multiple RF wire loops 210 or other RF members. In another embodiment, device 202 may include one or more blades as well as RF wire loop 210. In such an embodiment, wire loop 210 may be used to remove or otherwise modify soft tissues, such as ligamentum flavum, or to provide hemostasis, and blades may be used to modify hard tissues, such as bone. In other embodiments, as described further below, two separate tissue modification devices (or more than two devices) may be used in one procedure to modify different types of tissue, enhance modification of one type of tissue or the like.

In other alternative embodiments, tissue modification devices 202 may include tissue modifying members such as a rongeur, a curette, a scalpel, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal a cryogenic probe, a pressurized water jet, a drug dispensing element, a needle, a needle electrode, or some combination thereof. In some embodiments, for example, it may be advantageous to have one or more tissue modifying members that stabilize target tissue, such as by grasping the tissue or using tissue restraints such as barbs, hooks, compressive members or the like. In one embodiment, soft tissue may be stabilized by applying a contained, low-temperature substance (for example, in the cryo-range of temperatures) that hardens the tissue, thus facilitating resection of the tissue by a blade, rasp or other device. In another embodiment, one or more stiffening substances or members may be applied to tissue, such as bioabsorbable rods.

Referring now to FIGS. 5A-5D, one embodiment of a method for modifying tissue in a spine is demonstrated in simplified, diagrammatic, cross-sectional views of a portion of a patient's back and spine. FIG. 5A shows a portion of the patient's back in cross section, with a portion of a vertebra, the spinal cord with branching nerve roots, and target tissue, which in this illustration is the ligamentum flavum and possibly a portion of the facet capsule. The target tissue is typically impinging directly on one or more of the group including nerve roots, neurovascular structures, dorsal root ganglia, cauda equina, or individual nerves.

In FIG. 5B, tissue modification device 102 has been positioned in the patient's back to perform a tissue modification procedure. Various methods, devices and systems for introducing device 102 into the patient and advancing it to the position for modifying tissue are described in further detail below. Generally, device 102 may be positioned via a percutaneous or open surgical procedure, according to various embodiments. In one embodiment, device 102 may be inserted into the patient through a first incision 240, advanced into the spine and between target tissue and non-target tissue

15

(such as spinal cord, nerve roots, nerves and/or neurovascular tissue), and further advanced so a distal portion of elongate body **108** exits a second (or distal) incision **242** to reside outside the patient. In positioning device **102**, one or more tissue modifying members (not shown) are positioned to face the target tissue, while one or more protective portions of elongate body **108** face non-target tissue.

Referring to FIG. 5C, once device **102** is positioned in a desired location, anchoring force may be applied at or near the distal portion of elongate body **108**. In one embodiment, applying anchoring force involves a user **244** grasping body **108** at or near its distal portion. In alternative embodiments, as described further below, anchoring force may be applied by deploying one or more anchor members disposed at or near the distal portion of body **108**, or by grasping a guidewire or other guide member extending through at least part of body **108**. Once the anchoring force is applied, proximally-directed tensioning force may be applied to device **102**, such as by pulling proximally on handle **104** (one-directional, diagonal arrows). This tensioning force, when applied to the substantially anchored device **102**, may help urge the tissue modifying member(s) against the target tissue (one-directional, vertical arrows near target tissue), thus enhancing contact with the target tissue and facilitating its modification. With the tissue modifying member(s) contacting the target tissue, actuator **106** may be squeezed or pulled (two-headed arrow) to cause the tissue modifying member(s) to modify tissue. (Alternative actuators may be activated in different ways in alternative embodiments.)

In various alternative embodiments, certain of the above-described steps may be carried out in different order. For example, in one embodiment the distal portion of elongate body **108** may be anchored within or outside the patient before the tissue modifying members are positioned adjacent the target tissue. In another alternative embodiment, the proximal portion of device **102** may be anchored, and the tensioning force may be applied to the distal portion of device **102**. In yet another embodiment, tensioning force may be applied to both ends of the device. In yet another embodiment, a second handle and actuator may be coupled with the distal end of body **108** after it exits the patient's back, allowing tensioning forces as well as tissue modifying actuation to occur at both the proximal and distal portions of device **102**. By anchoring one end of device **102** and applying tensioning force to the opposite end, contact of the tissue modifying members with the target tissue is enhanced, thus reducing or eliminating the need for translating or otherwise moving device **102** as a whole and reducing the overall profile and the resulting access pathway required to position the device. Reducing movement and profile of device **102** and using tissue modifying members confined to a relatively small area of device **102** helps facilitate target tissue modification while minimizing or eliminating damage to surrounding tissues or structures.

As mentioned above, tissue may be modified using one tissue modification device or multiple devices, according to various embodiments. In one embodiment, for example, an RF electrosurgical tissue modification device may be used in the patient to remove soft tissue such as ligament, and a bladed tissue modification device such as a rongeur may then be used to remove additional soft tissue, calcified soft tissue, or hard tissue such as bone. In some embodiments, such multiple devices may be inserted, used and removed serially, while in alternative embodiments such devices may be inserted into the patient at the same time to be used in combination.

16

Referring to FIG. 5D, using one or more tissue modification devices **102**, a desired amount of target tissue may be removed from more than one area in the spine. FIGS. 5A-5C demonstrate removal of target tissue on one side of the spine, and that method or a similar method may also be used to remove target tissue on an opposite side of the spine, as shown in FIG. 5D, where target tissue has been removed from both sides. That the desired amount of tissue has been removed may be confirmed by tactile feedback from the device or from a separate device, by testing nerve conduction through one or more previously impinged nerves, by testing blood flow through one or more previously impinged blood vessels, by passing (independently or over the guide member) a measurement probe or sound through the treated portion, through one or more radiographic tests, through some combination thereof, or by any other reasonable means.

Referring now to FIG. 6A, tissue modification device **102** is shown with one embodiment of a distal anchoring member **250** deployed at the patient's skin. In various embodiments, anchoring members may include but are not limited to one or more handles, barbs, hooks, screws, toggle bolts, needles, inflatable balloons, meshes, stents, wires, lassos, backstops or the like. In some embodiments, anchoring members **250** may be disposed at the extreme distal portion **109** of elongate body **108**, while in other embodiments anchoring members **250** may be located more proximally. In the embodiment shown, anchoring members **250** are deployed at the patient's skin. In an alternative embodiment, anchoring may be achieved outside the patient by deploying one or more anchoring members **250** above the skin and having a user grasp the anchoring members **250**. In an alternative embodiment, anchoring may be achieved outside the patient by deploying one or more anchoring members **250** above the skin and having a user grasp anchoring members **250**, after tissue modification device **102** has been anchored to the guide member. In another alternative embodiment, anchoring may be achieved outside the patient by attaching anchoring member **250** to an external device, for example one that is mounted on the patient or on the procedure table. In a further alternative embodiment, anchoring may be achieved outside the patient by attaching the guide member to an external device, for example one that is mounted to on the patient or on the procedure table, after tissue modification device **102** has been anchored to the guide member. Anchoring members **250** generally are deployable from a first, contracted configuration to facilitate delivery of device **102**, to a second, expanded configuration to facilitate anchoring. This change in configuration may be achieved, for example, by using shape memory or super-elastic materials, by spring loading anchoring members **250** into body **108** or the like. In most embodiments, anchoring members **250** may also be collapsed down into the first, contracted configuration after a tissue modification procedure has been performed, to facilitate withdrawal of device **102** from the patient. In an alternative embodiment, anchoring members **250** may detach from body **108** and may be easily removable from the patient's skin.

FIG. 6B shows tissue modification device **102** with an alternative embodiment of a distal anchoring member **260**. Here, distal anchoring member **260** includes multiple hooks or barbs extended out the distal portion **109** of elongate body **108** within the patient's back. In using such an embodiment, it may not be necessary to pass guide member **117** through a second, distal incision on the patient, although in some embodiments guide member **117** may extend significantly beyond distal portion **109**. Anchoring member(s) **260**, according to various embodiments, may be deployed so as to anchor to bone, ligament, tendon, capsule, cartilage, muscle,

17

or any other suitable tissue of the patient. They may be deployed into vertebral bone or other suitable tissue immediately adjacent an intervertebral foramen or at a location more distant from the intervertebral foramen. When a tissue modification procedure is complete, anchoring members **260** are retracted within elongate body for removal of device **102** from the patient.

Referring now to FIGS. 7A-7S, a system and method for introducing a tissue modification device into a spine is demonstrated. This system and method may be referred to as an "access system" or "access method," in that they provide or facilitate gaining access to a target tissue to be modified. Of course, the embodiment shown is merely one exemplary embodiment, and any of a number of other suitable methods, devices or systems may be used to introduce one or more devices for modifying tissue in spine. For example, in one alternative embodiment a spinal tissue modification procedure may be carried out through an open surgical approach. Therefore, the following description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is defined in the claims.

Referring to FIG. 7A, in one embodiment a device delivery method first involves advancing an introducer cannula **300** coupled with a stylet **302** into the patient's back. Cannula **300** and stylet **302** are then passed between adjacent vertebrae and into the ligamentum flavum or an adjacent spinal ligament, as shown further in FIG. 7B. As shown in FIG. 7C, when the distal tip of cannula is positioned as desired, stylet **302** is removed. Referring to FIGS. 7D and 7E, a loss of resistance syringe **304** including a plunger **310**, barrel **308** and fluid and/or air **306**, is coupled with the proximal portion of cannula **300**. The distal portion of cannula **300** is advanced through the ligamentum flavum until it enters the central spinal canal where a loss of resistance to pressure placed on plunger **310** is encountered, and fluid and/or air **306** is injected into central spinal canal to confirm correct placement of cannula **300** as shown in FIG. 7E. Syringe **304** is then removed, as in FIG. 7F, and a guidewire **312** with a non-rigid, atraumatic tip is advanced through cannula **300** into the central spinal canal, as in FIG. 7G. Next, cannula **300** is removed, as in FIG. 7H, leaving behind guidewire **312**. As shown in FIGS. 7I and 7J, an introducer sheath **114**, coupled with a dilator **314**, is then advanced over guidewire **312** to position a distal portion of sheath **114** at a desired location within the spine. Dilator **314** and guidewire **312** are then removed, as in FIG. 7K.

Once introducer sheath **114** is in place, one or more curved or steerable guide devices **318** may be advanced through it to desired positions in and/or through the spine, as shown in FIGS. 7L and 7M. One or more guide members **116**, may then be advanced through the guide device **318**, as shown in FIGS. 7N-7P. Finally, guide device **318** may be removed, as in FIG. 7Q, and elongate body **108** of tissue modification device **102** may be advanced over guide member **116** and through introducer sheath **114** to a desired position in the spine, as in FIG. 7R. As shown in FIG. 7S, elongate body **108** may be tensioned to urge tissue modifying members **110** against target tissue, as shown with arrows at opposite ends of device **102**, while distal portion **109** is anchored, in this case by hand **244**. In an alternative embodiment, guide member **116** may be tensioned to urge tissue modifying members **110** against target tissue as shown in FIG. 7R.

Once tissue modification device **102** is in a desired position, tissues which may be modified in various embodiments include, but are not limited to, ligament, tendon, tumor, cyst, cartilage, scar, "bone spurs," inflammatory bone and joint capsule tissue. In some embodiments, modifying the target

18

tissue reduces impingement of the tissue on a spinal cord, a branching nerve or nerve root, a dorsal root ganglia, and/or vascular tissue in the spine. Actuator **106** on handle **104** is activated to modify target tissue using tissue modification member(s) **110**, while elongate body **108** is held relatively stable by hand **244** and by tension force applied to handle **104**.

In various embodiments, the system and method described immediately above may include additional features or steps, may have fewer features or steps, may have an alternate order of implementation of steps, or may have different features or steps. For example, in some embodiments placement of device **102** will be performed in a medial-to-lateral direction (relative to the patient), while in alternative embodiments device placement will be performed lateral-to-medial. In some embodiments, one or more components of the system described may be anchored to the patient, such as guide member **116** or introducer sheath **114**. In various embodiments, one or more guide members **116** may include one or more wires, rails or tracks and may be inserted through guide device **318**, introducer sheath **114** without guide device **318**, cannula **300**, an epidural needle, a lumen of an endoscope, a lumen of a tissue shield or barrier device, a curved guide device **318** placed through a lumen of an endoscope, or the like. In other embodiments, for example, guide device **318** may be placed through introducer cannula **300** and then introducer sheath **114** may be passed over guide device **318**. Tissue modification device **102** may similarly be inserted with or without using any of these devices or components in various combinations. Various guidewires **312**, guide devices **318** and/or guide members **116** may be pre-shaped to have one or more curves, may be steerable, and/or may include one or more rails, tracks, grooves, lumens, slots, partial lumens, or some combination thereof.

In some embodiments, tissue modification device **102** is inserted through one or more hollow devices as described above (such as introducer sheath **114**, as shown, or cannula **300** in an alternative embodiment) in such a way that device **102** expands upon extending out of a distal portion of the hollow delivery device thereby assuming a wider profile for modifying a greater amount of target tissue from a single location. In an alternative embodiment, device **102** retains the same overall profile during insertion and during use. In some embodiments, one or more delivery devices will remain in the patient during use of tissue modification device **102**, while in alternative embodiments all delivery devices are removed from the patient when tissue modification device **102** is operating. In some embodiments, tissue modification device **102** may be slidably coupled with one or more delivery devices during delivery and/or during use. In one embodiment, tissue modification device **102** is advanced through introducer sheath **114** and sheath **114** is used as an irrigation and evacuation lumen to irrigate the area of the target tissue and evacuate removed tissue and other debris, typically by applying a vacuum. In alternative embodiments, tissue modification device **102** may include an irrigation and/or evacuation lumen to irrigate an area of the target tissue and evacuate removed tissue and other debris.

Some embodiments of an access system for facilitating tissue modification may further include one or more visualization devices (not shown). Such devices may be used to facilitate placement of the access system for introducing the tissue modification device, to facilitate tissue modification itself, or any combination of these functions. Examples of visualization devices that may be used include flexible, partially flexible, or rigid fiber optic scopes, rigid rod and lens endoscopes, CCD or CMOS chips at the distal portion of rigid or flexible probes, LED illumination, fibers or transmission of

an external light source for illumination or the like. Such devices may be slidably couplable with one or more components of an access system or may be slidably or fixedly coupled with a tissue modification device. In other embodiments, additional or alternative devices for helping position, use or assess the effect of a tissue modification device may be included. Examples of other such devices may include one or more neural stimulation electrodes with EMG or SSEP monitoring, ultrasound imaging transducers external or internal to the patient, a computed tomography (CT) scanner, a magnetic resonance imaging (MRI) scanner, a reflectance spectrophotometry device, and a tissue impedance monitor disposed across a bipolar electrode tissue modification member or disposed elsewhere on a tissue modification device or disposed on the access system.

Referring now to FIGS. 8A-8E, in an alternative embodiment, a tissue modification device and optionally one or more introduction/access devices may be positioned in a patient using an open surgical technique. As shown in FIG. 8A, for example, in one embodiment an open surgical incision is made on a patient's back, and two retractors 402 are used to expose a portion of the patient's vertebra. As shown in FIG. 8B, an introducer sheath 414 may then be inserted through the incision, between retractors 402. As in FIG. 8C, a curved guide device 418 may then be inserted through introducer sheath 414. Guide device 418 extends into the epidural space and through the intervertebral foramen as shown in FIG. 8D.

In some embodiments, a curved and cannulated thin, blunt probe may be placed directly through the open incision into the epidural space of the spine, or alternatively may be placed through introducer sheath 414. The probe tip may be advanced to or through a neural foramen. Such a probe may be similar in shape, for example, to a Woodson elevator, Penfield 3, hockey stick probe, ball tipped probe, or the like. In alternative embodiments, probes that may be manually bent to change their shapes, or probes with articulating tips, or probes with shape lock portions, and/or probes having grooves instead of cannulas may be used.

As shown in FIGS. 8D-8E, a substantially straight, flexible guidewire 420 with a sharp tip 422 may then be inserted through curved guide device 418 and advanced so that its distal portion with sharp tip 422 extends outside the patient's back at a location separate from the open incision (FIG. 8E). Guide device 418 may then be removed, as in FIG. 8F, and in subsequent steps a tissue modification device may be inserted over guide wire 420 and through introducer sheath 414 and used to modify tissue as described in more detail above. In an alternative embodiment, a curved, flexible cannula may be inserted through the curved guide device, until it extends lateral to the neural foramen, after which a substantially straight, flexible guidewire with a sharp tip may then be inserted through curved cannula and advanced so that its distal portion with sharp tip extends outside the patient's back.

Referring now to FIGS. 9A and 9B, another alternative open surgical access method is shown. In FIG. 9A, a curved guide device 446 is shown in place through the epidural space and intervertebral foramen, and a guidewire 440 with a beveled distal tip 442 is about to be advanced through guide device 446. As shown in FIG. 9B, in this embodiment, guidewire 440 is directed by guide device 446 back through the open incision through which the various access devices are introduced. In such an embodiment, then, only one incision is created and the proximal and distal portions of one or more devices extend out of the patient's back through the same incision.

In various alternative embodiments, open surgical access may be through exposure down to a vertebral lamina, through ligamentum flavum without lamina removal, through ligamentum flavum with partial or complete lamina removal, through ligamentum flavum with or without lamina removal with partial or complete medial facet joint removal, through open exposure and out through skin laterally, through open exposure and back out through the open exposure, or through a lateral open exposure that accesses the neural foramen from the lateral side. One or more visualization devices may be used with open surgical access procedures as well as with percutaneous or other less invasive procedures. In another alternative embodiment (not shown), a tissue modification device may be placed in the patient directly, without any introduction devices.

Referring now to FIGS. 10A-10E, in the embodiments described above, the tissue modification devices 102, 202 include at least one non-tissue-modifying (or "protective") portion, side or surface. The non-tissue-modifying portion is located on tissue modification device 102, 202 so as to be positioned adjacent non-target tissue when tissue modifying members 110, 210 are facing the target tissue. The non-tissue-modification surface of the device is configured so as to not modify or damage tissue, and thus the non-target tissue is protected from unwanted modification or damage during a tissue modification procedure.

Optionally, in some embodiments, tissue modification devices or systems may further include one or more tissue shields or barriers for further protecting non-target tissues. Such shields may be slidably coupled with, fixedly coupled with, or separate from the tissue modification devices with which they are used. In various embodiments, a shield may be delivered between target and non-target tissues before delivering the tissue modification device, may be delivered along with the tissue modification device, or may be delivered after delivery of the tissue modification device but before the device is activated. Generally, a shield will be interposed between the non-target tissue and the tissue modification device.

FIG. 10A shows a distal portion of an introducer device 514 through which a shield may be introduced. FIGS. 10B and 10C show one embodiment of a shield device 500 (or "barrier device") partially deployed and in cross-section, respectively. Typically, shield 500 will have a first, small-profile configuration for delivery to an area near non-target tissue and a second, expanded configuration for protecting the non target tissue. Shield itself may be configured as one piece of super-elastic or shape-memory material, as a scaffold with material draped between the scaffolding, as a series of expandable wires or tubes, as a semicircular stent-like device, as one or more expandable balloons or bladders, as a fan or spring-loaded device, or as any of a number of different devices configured to expand upon release from a delivery device to protect tissue. As shown in FIGS. 10B and 10C, shield 500 may comprise a sheet of material disposed with a first end 502a abutting a second end 502b within introducer device 514 and unfurling upon delivery. In an alternative embodiment, as shown in FIGS. 10D and 10E, opposite ends 522a and 522b of a shield device 520 may overlap in introducer device 514. Generally, shield 500, 520 may be introduced via introducer device 514 in one embodiment or, alternatively, may be introduced via any of the various means for introducing the tissue modification device, such as those described in conjunction with FIGS. 7A-7S, 8A-8F and 9A-9B. In some embodiments, shield 500, 520 may be fixedly coupled with or an extension of a tissue modification device. Shield 500, 520 may also include one or more lumens, rails,

21

passages or the like for passing a guidewire or other guide member, for introducing, removing or exchanging any of a variety of tissue modification, drug delivery, or diagnostic devices, for passing a visualization device, for providing irrigation fluid at the tissue modification site, and or the like. In some embodiments, shield 500, 520 is advanced over multiple guidewires and the guidewires remain in place during a tissue modification procedure to enhance the stability and/or maintain positioning of shield 500, 520.

With reference now to FIG. 11, in some embodiments a tissue modification device 600 may include an elongate, at least partially flexible body 602, an abrasive tissue modifying surface 604, a proximal handle 606 and a distal handle 608. As has been mentioned above, in some embodiments abrasive surface 604 may comprise any of a number of various abrasive members, configurations or the like, such as but not limited to a rasp. Various abrasive surface/rasp embodiments, for example, are described in further detail in PCT Patent Application Pub. No. PCT/US2005/037136, which was previously incorporated by reference. For example, embodiments including abrasive or rasp surfaces are described in FIGS. 34, 35, 41, 42, 48, 61, 62, 64, 86-99, 101 and 102, and their accompanying detailed description in PCT Patent Application No. PCT/US2005/037136 (Publication No. WO 2006/044727).

In use, the distal end of elongate body 602 may be advanced through the patient's back, into the epidural space, between target and non-target tissue, and out the patient's back, as in FIG. 11. Distal handle 608 may then be removably coupled with the distal end of elongate body 602 (or near the distal end in alternative embodiments). A user may then grasp proximal handle 606 and distal handle 608 and pull on both to apply tensioning force (solid-tipped, upward-pointing arrows) to urge abrasive surface 604 against the target tissue. The user may also use handles 606, 608 to translate elongate body 602 back and forth (double-headed arrows) to cause abrasive surface 604 to abrade the target tissue. During a given tissue modification procedure, tensioning force may be applied, using separate handles 606, 608, by pulling handles 606, 608 in different directions or in the same direction (i.e., parallel to one another). In some procedures, handles 606, 608 may be moved about to apply tensioning force from different angles and directions during the procedure. As mentioned above, by "separate handles," it is meant that handles 606, 608 are not connected to one another by a common handle or other connecting device or mechanism. Obviously, however, handles 606, 608 may be coupled with (in some embodiments removably coupled with) elongate body 602 (or a shield in other embodiments) at or near its distal and proximal ends or portions.

Elongate body 602 may have any suitable dimensions, according to various embodiments. In some embodiments, elongate body 602 is sufficiently long to extend from outside the patient, through a channel in the spine, such as an intervertebral foramen, and out of the patient through an exit point located apart from the entry point. Elongate body 602 will typically have a width sufficient to prevent abrasive surface 604 from cutting completely through bone when tensioning force is applied and body 602 is translated. For example, in one embodiment, body 602 may have a width (at least along a portion where abrasive surface 604 is disposed) of about 3 mm or less, and more preferably about 5 mm or less. Body 602 may also have a height that facilitates its passage into the patient and between target and non-target tissues. For example, in one embodiment, body 602 has a height of about 4 mm or less, and more preferably about 2 mm or less.

22

In some embodiments, abrasive surface 604 may be disposed along one side of elongate body 602 and along a limited length of elongate body 602, to prevent or minimize unwanted damage to nearby non-target tissues as elongate body 602 is translated. For example, in some embodiments, abrasive surface 604 may be disposed along a length of the device measuring no longer than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. In alternative embodiments, abrasive surface 604 may extend along a substantial majority or even the entire length of elongate body 602 and/or may reside on multiple sides of elongate body 602. In one embodiment, for example, all of elongate body 602 may comprise abrasive surface 604, and at least a portion of elongate body 602 may be disposed within a shield or barrier member to protect non-target tissues from damage during a procedure. Some embodiments, however, include at least one non-abrasive side or surface adjacent abrasive surface 604, to protect non-target tissue from unwanted damage. Such a non-abrasive surface may optionally be made of a lubricious or low-friction material and/or may be coated with a lubricious or low-friction coating, in some embodiments.

Proximal handle 606 and distal handle 608 may have any size, shape or configuration in various embodiments. In fact, in various embodiments, distal handle 608, proximal handle 606, or both may be left off altogether. In FIG. 11, proximal handle 606 is shown as a squeezable handle with a trigger, as has been described previously for use with a bladed, RF or other movable tissue modifying member (or members). Such a squeezable handle 606 is not required in every embodiment, but may be used in some embodiments, such as when an abrasive/rasp device 600 may be interchanged with a bladed device, RF device and/or the like during a tissue modification procedure. Thus, in some embodiments, squeezable proximal handle 606 is removably coupleable with elongate body 602, so that various alternative tissue modifying members may be used with the same proximal handle 602. In such embodiments, for example, target tissue may be modified using rasp elongate body 602 and then may be further modified using an RF device, bladed device, powered device or the like. In various embodiments, such devices may be used in any order. Similarly, distal handle 608 may also be used with more than one device.

In some embodiments, tissue modification device 600 may further include one or more electrodes (not shown) coupled with or immediately adjacent abrasive surface 604 and/or non-abrasive surface(s) of elongate body 602. Such electrodes may be activated, for example, via a trigger or button on proximal handle 606 in order to test positioning of abrasive surface 604 within the patient. For example, once a user believes abrasive surface 604 to be in position for treating target tissue, an electrode on abrasive surface 604 may be activated. If abrasive surface 604 is actually in contact with nerve tissue, which the user does not want to treat or damage, the patient's leg may twitch or jerk, showing the user that abrasive surface 604 should be repositioned or the procedure aborted. Alternatively or additionally, an evoked EMG response of a patient may be monitored to determine if the activated electrode is touching or near nerve tissue. In another embodiment, electrode may be placed on a non-abrasive surface, so that when activated, it demonstrates that the non-abrasive surface is facing non-target tissue, as intended. In various embodiments, any combination of electrodes may be used. Further description of such electrodes and their use can be found in PCT Patent Application Pub. No. PCT/US2005/037136.

Referring now to FIGS. 12A-12D, in various embodiments, a rasp or abrasive surface of a tissue modification

23

device may have any of a number of suitable configurations, sizes, numbers of rasp elements and/or the like. A number of such abrasive surfaces, for example, are described in previously incorporated PCT Patent Application No. PCT/US2005/037136 (Publication No. WO 2006/044727), such as in FIGS. 90-96 and the accompanying detailed description. The embodiments shown in FIGS. 12A-12D are further examples of rasp/abrasive surface configurations, according to various embodiments.

In one embodiment, as shown in FIG. 12A, a diagonally patterned rasp member 624 having multiple notches 626 may be disposed along one side of an elongate body 622 of a tissue modification device. Of course, in various embodiments, rasp member 624 may have any number of bends or may have any other alternative shape or configuration. In alternative embodiments, rasp member 624 may be made of any of the materials listed in the foregoing description for any alternative embodiments of tissue modifying members. For example, in some embodiments, rasp member 624 may have hard edge and be comprised of a material like stainless steel or titanium, while in other embodiments rasp member 624 may be fabricated as an abrasive surface of diamond, tungsten carbide or the like. In yet another embodiment, a braided wire, such as the braided wire used in a Gigli saw, may be adhered to a surface of elongate body 622 to form rasp member 624. Obviously, rasp member 624 may have any of a number of configurations and may be fabricated from any suitable material, and thus, rasp member 624 is not limited to the examples described here.

FIG. 12B shows an alternative embodiment, in which a rasp member 634 and multiple channel openings 636 are disposed along an elongate body 632 of a tissue modification device. In such an embodiment, tissue that is abraded off by rasp member 634 may enter channel openings 636 into a hollow portion (or multiple hollow portions) of elongate body 632. In various embodiments, removed tissue may be either stored in such a channel and removed when the tissue modification device is removed from the patient, or may alternatively be directed out of elongate body 632 using irrigation, suction or a combination thereof.

In another embodiment, shown in FIG. 12C, a rasp portion 644, disposed along an elongate body 642, may include any number of rasp members 646 and, optionally, any number of channel openings 648. In some embodiments, rasp members 646 may have cutting edges that face in the same direction. In such embodiments, rasp members 646 abrade or cut tissue when elongate body 642 is translated in one direction and do not abrade or cut tissue when translated in the opposite direction. In various embodiments, rasp members 646 may also be configured to direct tissue in channel openings 648.

FIG. 12D shows another embodiment of a rasp portion 654 disposed along an elongate body 652 of a tissue modification device. Rasp portion 654 again includes multiple rasp members 656 and multiple channel openings 658, but in this embodiment, rasp members 656 have alternating rows of oppositely directed cutting edges. Thus, when elongate body 652 is translated back and forth, rasp members 656 abrade or cut tissue as elongate body 652 travels in both directions.

With reference now to FIG. 13, in an alternative embodiment, a tissue modification device 700 may include an elongate, at least partially flexible body 702, at least part of which is disposed within a shield member 710 (or "barrier member") having an opening 712 along its length. Elongate body 702 may include at least one abrasive surface 704, which may comprise a rasp or other abrasive surface as discussed above, and which may be exposed through opening 712 to contact and abrade target tissue. Tissue modification device 700 may

24

also include a proximal handle 706 and a distal handle 708, either or both of which may be removably coupled with elongate body 702, according to various embodiments. Shield member 710 may optionally include a proximal anchoring member 714 and/or a distal anchoring member 716 for anchoring shield member 710 outside the patient. In alternative embodiments, proximal handle 706, distal handle 708, or both may be coupled with shield member 710, rather than with body 702.

In use, shield member 710 may be passed into the patient's back, into the epidural space, between target and non-target tissue, and out the patient's back. In various embodiments, elongate body 702 may be passed into the patient along with shield member 710 or through shield member 710 after it is in place. In another embodiment, elongate body 702 may be passed into patient first, and shield member 710 may be passed over it into the patient. Abrasive surface 704 may be positioned so that it is exposed and/or protrudes through opening 712 on shield member 710 to contact target tissue. Tensioning force may be applied to shield member 710, elongate body 702, or both, to urge abrasive surface 704 into the target tissue. For example, in some embodiments, tensioning force may be applied by grasping and pulling on handles 706, 708, while in other embodiments, tensioning force may be applied by grasping and pulling on distal and proximal portions of shield member 710. At some point, either before or after applying tensioning force, anchoring members 714, 716 may be coupled with or deployed from shield member 710. Various alternative embodiments may include only proximal anchoring member 714 or only distal anchoring member 716, and the unanchored end of shield member 714 may be pulled to apply tensioning force. Anchoring members 714, 716 may include any suitable device for anchoring or leveraging against the patient's skin, some exemplary embodiments of which are described above in connection with FIG. 6A. In alternative embodiments, anchoring members 714, 716 may attach to one or more devices apart from the patient, such as a rail of an operating table or the like. In other alternative embodiments, shield member 710 may be held relatively stationary by manually holding one or both of its ends. In other embodiments, shield member 710 may be held relatively stable simply by residing in the patient's own tissue. In further alternative embodiments, both shield member 710 and body 702 may be held relatively stable, and one or more actuators on proximal handle 706 and/or distal handle 708 may be used to move or otherwise activate abrasive surface 704 to abrade the target tissue.

Elongate body 702 may be translated back and forth through shield member 710 to cause abrasive surface 704 to abrade target tissue. Because shield member 710 generally protects non-target tissue from unwanted damage, abrasive surface 704 may be disposed along elongate body for any desired length and/or may be disposed about all or substantially all of the circumference of elongate body 702. In some embodiments, for example, abrasive surface 704 may extend the entire length of elongate body 702. In fact, in some embodiments, elongate body 702 may comprise a rasp, braided wire saw or the like. In some embodiments, shield member 710 may include one or more protective materials, added layers of material, or the like (not shown) along one or more edges of opening 712, to prevent damage to such edges of opening 712 when elongate body 702 is translated back and forth.

In various embodiments, either shield member 710, elongate body 702, or both may include additional features to enhance a tissue modification procedure to treat or alleviate spinal stenosis. For example, in various embodiments, shield

25

member **710** and/or elongate body **702** may include one or more lumens for applying suction and/or irrigation, to help remove tissue debris from the patient. Such debris may be removed through one or more lumens in shield member **710**, one or more lumens in elongate body **702**, or between shield member **710** and elongate body **702**, in various embodiments. Optionally, one or more electrodes may be positioned on shield member **710**, elongate body **702**, abrasive surface **704** or some combination thereof, to help allow a user to verify device **700** is in a desired location in the patient, as described above. In various embodiments, other optional features may also be added.

Turning now to FIGS. **14A** and **14B**, in another embodiment, a tissue modification device **800** may include an elongate body **802**, a widened tissue modifying portion **806** including an abrasive surface **808**, tapered portions **810** and a non-abrasive surface **816**, a proximal handle **812** and a distal handle **814**. (FIG. **14B** shows a side view of a portion of device **800**.) In one embodiment, elongate body **802** may comprise a metal wire, and tissue modifying portion **806** may comprise a wider section coupled with the wire. Body **802**, tissue modifying portion **806** and the like may have any suitable size and configuration, and abrasive surface **808** may have any suitable configuration, examples of which have been described in greater detail above and in PCT Patent Application No. PCT/US2005/037136 (Publication No. WO 2006/044727), which was previously incorporated by reference. In various embodiments, body **802** may be coupled with tissue modifying portion **806** using any technique, such as welding, attaching with adhesive or the like. In an alternative embodiment, body **802** and tissue modifying portion are formed from one piece of material. Optionally, body **802** and/or tissue modifying portion **806** may include one or more lumens, such as a guidewire lumen, suction lumen, irrigation fluid lumen and/or the like. Device **800** may also include a shield member, one or more electrodes, or any of the additional features described above in conjunction with other embodiments.

Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. For example, in many of the embodiments described above, one or more abrasive tissue modifying members may be substituted for one or more bladed tissue modifying members or vice versa. These and many other modifications may be made to many of the described embodiments. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

What is claimed is:

1. A device for modifying tissue in a spine of a patient, the device comprising:

- a flexible elongate body having a tapered distal portion that is configured to couple to a guidewire and to be passed through a first incision on the patient's back into the spine between target and non-target tissues, and out a second incision on the patient's back;
- a handle at a proximal end of the flexible elongate body;
- a tissue modifying region comprising at least one wire between the tapered distal portion and the handle;

26

a shield member housing attached to the flexible elongate body adjacent to the tissue modifying region, wherein the shield member housing includes a shield receiving space therein; and

a shield member movably coupled to at least one of the shield member housing and the flexible elongate body, wherein the shield member is selectively deployable from within the shield receiving space to at least partially cover the tissue modifying region for preventing a non-target tissue from being modified by the tissue modification member.

2. The device of claim 1, wherein the tissue modifying region comprises an abrasive surface.

3. The device of claim 1, wherein the shield member comprises at least one opening along its length.

4. The device of claim 1, wherein the shield member comprises a hollow member having an opening in a sidewall of the hollow member.

5. The device of claim 1, further comprising a second handle configured to apply tension to the distal portion of the elongate body.

6. The device of claim 1, wherein the shield member comprises an opening extending along one side of the entire length of the shield member.

7. The device of claim 1, wherein the shield member comprises at least one anchoring member for anchoring or leveraging against the patient's skin, the anchoring member being coupled with the shield member outside the patient.

8. The device of claim 1, wherein the shield member comprises: a proximal anchor member; and a distal anchor member.

9. A device for modifying tissue in a spine of a patient, the device comprising:

a flexible elongate body extending externally through a first incision and a second incision on the patient's back distally to proximally;

a shield member housing attached to the flexible elongate body, wherein the shield member housing includes a shield member receiving space therein;

an elongate flexible shield member having a proximal portion and a distal portion, wherein the shield member is selectively extendable from within the shield member receiving space for allowing a portion of the shield member extending from within the shield member housing to be adjusted;

a flexible tissue modification member forming a portion of the flexible elongate body, wherein the tissue modification member is disposed at least partly within the shield member, wherein the tissue modification member has a proximal portion, a distal portion, and at least one abrasive region between the proximal and distal portions, and wherein the at least one abrasive region is adjacent to the shield member such that a portion of the at least one abrasive region covered by the shield member is correspondingly adjusted as the portion of the shield member extending from within the shield member housing is adjusted; and

a proximal handle coupled to the flexible elongate body and configured to provide proximal tensioning at or near the proximal portion of at least one of the shield member and the tissue modification member for facilitating application of tensioning force in a first direction on the flexible tissue modification member by grasping the proximal handle and pulling.

10. The device of claim 9, wherein the shield member comprises at least one opening along its length.

27

11. The device of claim 9, wherein the shield member comprises a hollow member, and the opening comprises a window in a sidewall of the hollow member.

12. The device of claim 9, wherein the tissue modification member comprises at least one wire.

13. The device of claim 9, wherein the portion of the shield member selectively extendable from within the shield member receiving space includes a sheet of material that unfurls in response to the shield member being extended from within the shield member receiving space.

14. The device of claim 9, wherein the shield member comprises an opening extending along one side of the entire length of the shield member.

15. The device of claim 9, wherein the shield member is removably coupled with the tissue modification member.

16. The device of claim 9, wherein the shield member comprises at least one anchor for anchoring the shield member outside the patient.

17. The device of claim 9, wherein the shield member comprises: a proximal anchor; and a distal anchor.

18. The device of claim 9, wherein the shield member includes a guidewire coupler at the distal end of the elongate body.

28

19. A device for modifying tissue in a spine of a patient, the device comprising:

a flexible elongate body including a shield receiving space therein, the flexible elongate body having a distal end and a proximal end extending externally through a first incision and a second incision on the patient's back;

a handle at the proximal end of the flexible elongate body; a tissue modifying region comprising at least one wire between the distal end and the handle; and

a shield member movably coupled to the flexible elongate body for allowing the shield member to be selectively deployed from within the shield receiving space, wherein the shield member at least partially covers the tissue modifying region when deployed from within the shield receiving space to prevent a non-target tissue from being modified by the tissue modification member;

wherein the device is configured to couple to a guidewire and to be passed into a spinal region between a target tissue and the non-target tissue and extending through the first incision on the patient's back on the proximal end out the second incision on the patient's back to the distal end.

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